In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 11-852V
January 31, 2017
To be Published

L.A.M.,	*	
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Petitioner,	*	Human papillomavirus ("HPV") vaccine
	*	("Gardasil"); migraines; postural
v.	*	orthostatic tachycardia syndrome
	*	("POTS"); chronic fatigue syndrome;
SECRETARY OF HEALTH	*	conversion disorder; undifferentiated
AND HUMAN SERVICES,	*	connective tissue disease ("UCTD");
	*	small fiber polyneuropathy.
Respondent.	*	

Patricia A. Finn, Piermont, NY, for petitioner.
Debra A. Filteau Begley, Gordon Shemin, Lara A. Englund, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

On December 6, 2011, when petitioner was still a minor, her father[2] filed a petition pro se under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10–34 (2012), alleging that human papillomavirus vaccine ("Gardasil") administered on December 3, 2008 caused his

[1] Vaccine Rule 18(b) states that special masters shall make all decisions available to the public unless the decision contains trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When a special master files a decision, a petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access. See also 42 U.S.C. § 300aa-12(d)(4)(B)(i) and (ii). Because petitioner requested the court reporter at trial to redact her name to initials, being under the impression that the transcript would be publicly available (which is not the case), the undersigned is cognizant that petitioner would want this decision also to be redacted. Therefore, *sua sponte*, the undersigned redacts it without petitioner's motion.

[2] Petitioner's father is a thoracic and cardiac surgeon at the medical center where petitioner received most of her medical care.

daughter severe and debilitating headaches, photophobia,[3] phonophobia,[4] extreme fatigue, dizziness, and gait disturbances. Pet. Preamble & ¶ 2. His daughter having reached the age of majority, on February 2, 2012, the original petitioner moved to substitute his daughter as petitioner, which motion the undersigned granted. The current petitioner is the vaccinee.

From December 6, 2011 until June 25, 2012, petitioner's father (at that time, he was petitioner) did not file any medical records. On June 25, 2012, petitioner's father advised the undersigned during a telephonic status conference he attended with petitioner that petitioner had retained the services of an attorney, Patricia A. Finn. On July 16, 2012, Ms. Finn moved to substitute as attorney of record, which the undersigned granted. Ms. Finn said she would obtain and file the medical records.

On October 19, 2012, petitioner filed a Certificate of Completion, stating that she had filed a complete set of medical records.

On November 13, 2012, the undersigned issued an Order to Show Cause why the case should not be dismissed based on the medical records showing that the same symptoms about which petitioner complained Gardasil caused had occurred prior to vaccination on two occasions, i.e., in May and June 2007, which her treating doctors attributed to a virus. The undersigned suggested in the Order to Show Cause that if petitioner wanted to continue her petition, she should amend her petition to allege significant aggravation. In addition, the undersigned noted in the Order to Show Cause that the symptoms about which petitioner complained Gardasil caused had occurred two months after her second Gardasil vaccination in the immediate aftermath of a sore throat, fever, and swollen glands on February 15, 2009, suggesting that this diagnosed upper respiratory viral infection triggered the resumption of her pre-vaccination symptoms.

On November 16, 2012, the undersigned held a telephonic status conference with counsel during which petitioner's counsel asked for 90 days to find an expert.

On February 25, 2013, the undersigned held another telephonic status conference with counsel during which petitioner's counsel said she had contacted Dr. Yehuda Shoenfeld, an immunologist, who was willing to provide an opinion, which she expected in a month.

Four months later, on June 24, 2013, petitioner filed Dr. Shoenfeld's response to the questions the undersigned raised in her November 13, 2012 Order to Show Cause (Exhibit 24) and also filed Dr. Shoenfeld's expert report (Exhibit 38). In his response to the Order to Show Cause, Dr. Shoenfeld attributed petitioner's condition to aluminum adjuvant in Gardasil vaccine, basing his analysis on a theory of autoimmune (auto-inflammatory) syndrome induced by adjuvants ("ASIA"). Ex. 24, at 3 (the pages of the exhibit are unnumbered; the undersigned is

[3] Photophobia is "abnormal visual intolerance to light." Dorland's Illustrated Medical Dictionary 1441 (32nd ed. 2012) (hereinafter, "Dorland's").

[4] Phonophobia is "irrational fear of sounds or of speaking aloud." Dorland's at 1435.

using the CM-ECF numbering). In his expert report, Dr. Shoenfeld discusses the new ASIA syndrome, which he first described in 2011. Ex. 38, at 2. He also opines that Gardasil caused petitioner's postural orthostatic tachycardia syndrome ("POTS") and chronic fatigue syndrome ("CFS"). Id. at 6. He notes that POTS and CFS are manifestations of ASIA syndrome. Id. at 10.

On July 19, 2013, respondent filed the expert report of Dr. J. Lindsay Whitton, an immunologist, disputing the validity of Dr. Shoenfeld's ASIA hypothesis. Ex. A. On the same date, respondent filed the expert report of Dr. Edward W. Cetaruk, a toxicologist and specialist in emergency medicine, also disputing the validity of Dr. Shoenfeld's ASIA theory. Ex. VV.

On July 26, 2013, Dr. Shoenfeld responded to Dr. Cetaruk's expert report, defending the ASIA syndrome. Ex. 137. On August 8, 2013, Dr. Shoenfeld responded to Dr. Whitton's expert report, defending the ASIA syndrome. Ex. 249.

On December 6, 2013, respondent filed her Rule 4(c) Report, stating that petitioner did not have a compensable case.

Together with her Rule 4(c) Report, respondent filed reports from the following three experts:

(1) Dr. Carlos Rosé, a pediatric rheumatologist (Exhibit RRR);
(2) Dr. Max Wiznitzer, a pediatric neurologist (Exhibit BBBB); and
(3) Dr. Stephen McGeady, a pediatrician and immunologist (Exhibit MMMM).

On March 13, 2014, Dr. Shoenfeld responded to the expert reports of Dr. Rosé, Dr. McGeady, and Dr. Wiznitzer. Exs. 471, 472, and 473.

On November 18, 2014, petitioner filed the affidavit of her father. Ex. 551. He states that on or about February 15, 2009, petitioner developed a sore throat, fatigue, low grade temperature, and swollen glands, which lasted about one week. Id. at ¶ 5. He also states that on or about February 20, 2009, petitioner began to develop a headache and said it was about a 5 out of 10 on the pain scale. Id. at ¶ 6. On February 21, 2009, petitioner's headache worsened and was about 9 out of 10 on the pain scale. Id. at ¶ 7. She began to experience nausea, photophobia, and phonophobia, and she had no appetite and refused to eat or drink. She lay on a couch in a dark, quiet room and did not move. Id. On February 26, 2009, petitioner's primary care physician, Dr. Kennette, diagnosed her with migraines and prescribed Lortab and Imitrex. Id. at ¶ 8. Because the medications did not work, petitioner returned to Dr. Kennette on March 2, 2009. Id. at ¶ 9. Petitioner could not find her balance to walk, although she never had true vertigo or nystagmus. Id. Petitioner would seem to collapse onto the floor, explaining that her legs just went weak and she cried all day and night. Id. at ¶ 10. Petitioner was prescribed Depakene and Antivert, which also did not work. Id. On March 6, 2009, petitioner went to the Albany Medical Center Emergency Room and received Compazine, Toradol, and Benedryl. Id. at ¶ 11. Dr. Nichter, a pediatric neurologist, evaluated petitioner and she received Depacon,

Reglan, and Compazine. Id. Conversations with Dr. Nichter resulted in an increase in the dosage of Topamax and the beginning of multivitamins, vitamin B-2, melatonin for sleep, and Maxalt-MLT. Id. at ¶ 12. He increased her dosage of Topamax three more times. Id. at ¶¶ 12, 14, 17. On April 6, 2009, petitioner saw Dr. Nichter who ordered a steroid pulse and prescribed Dexamethasone. Id. at ¶ 16. On May 4, 2009, petitioner saw Dr. Magdi Sobeih, a pediatric neurologist at Boston Children's Hospital, who found nothing wrong with petitioner. Id. at ¶20. When Dr. Sobeih suggested petitioner see a psychiatrist or psychologist, petitioner told Dr. Sobeih her opinion of his diagnosis. Id. On May 21, 2009, petitioner saw Dr. Nichter who prescribed Elavil and told her to wean off Topamax. Id. at ¶ 23. He increased the dosage of Elavil three times. Id. at ¶¶ 24, 27, 30. He also prescribed Ativan. Id. at ¶ 30. Hypnosis failed to resolved petitioner's headaches. Id. at ¶ 31. On September 8, 2009, Dr. Nichter discontinued Ativan and started petitioner on Cymbalta. Id. at ¶ 32. On September 16, 2009, petitioner tried Reglan and Depakote, and a higher dosage of Inderal and Cymbalta. Id. at ¶ 34.

On October 6, 2009, petitioner saw Dr. Nichter because she was having syncopal episodes: she would see black spots and fall to the floor. Id. at ¶ 35. He noted petitioner had tachycardia, and weaned her off Inderal. Dr. Nichter said physical therapy was imperative. Id. On October 21, 2009, petitioner took Ambien for sleep issues. Id. at ¶ 37. On November 6, 2009, petitioner saw Dr. Charles Rheeman, a neuro-ophthalmologist, because she complained of difficulties with reading. Id. at ¶ 39. Dr. Rheeman examined petitioner and found her normal. Id. at ¶ 40. Dr. Rheeman thought stressors caused petitioner's difficulties with reading, which infuriated petitioner. Id. On December 4, 2009, Dr. Petri suggested petitioner take Plaquenil. Id. at ¶ 43. On December 17, 2009, petitioner took Midrodine for POTS. Id. at ¶ 44. On January 14, 2010, petitioner took Florinef. Id. at ¶ 45. On February 11, 2010, petitioner stopped taking Florinef and started taking Midrodine again, and the doctor increased the dosage March 11, 2010. Id. at ¶¶ 47, 49. On March 1, 2010, Neurontin was increased. Id. at ¶ 48. (The undersigned counts 23 medications listed in this affidavit, most of them for headache.)

On December 19, 2014, the parties filed a stipulation of interim attorneys' fees and costs. The undersigned issued a decision on the same date, awarding interim attorneys' fees and costs based on the stipulation.

On May 14, 2015, respondent filed a supplemental expert report of Dr. Rosé. Ex. AAAAAA.

On June 11, 2015, petitioner filed additional medical records. Exs. 552, 553.

On June 15, 2015, petitioner filed her affidavit. Ex. 554. Petitioner states that on February 15, 2009, she developed a sore throat, fatigue, a low-grade temperature, and swollen glands, which continued for about one week. Id. at ¶ 5. On February 20, 2009, she developed a very painful headache. Id. at ¶ 6. On February 21, 2009, her headache worsened and felt like it was 9 out of 10 on the pain scale. Id. at 7. She also had nausea, photophobia, and phonophobia. She had no appetite and refused to eat or drink. She lay on the couch in a dark, quiet room and

did not move. Id. Petitioner saw her primary care physician, Dr. Kennette, on February 26, 2009. Id. at ¶ 8. Dr. Kennette diagnosed her with migraines and prescribed Lortabs and Imitrex. Id. On May 4, 2009, petitioner saw Dr. Magdi Sobeih, a pediatric neurologist, who concluded there was nothing wrong with petitioner and suggested petitioner see a psychiatrist or psychologist, which petitioner stated was extremely upsetting to her and traumatized her. Id. at ¶ 16. She saw Dr. Steven Sandler, a pediatric psychiatrist, at the end of summer 2009, who told her he did not suspect her symptoms were psychosomatic, but his attempt to help her headaches with hypnosis failed. Id. at ¶ 25. Once petitioner started school in September 2009, her headaches worsened and her improvement in her ability to walk and her gait declined, resulting in her not attending school. Id. at ¶ 27. On October 6, 2009, petitioner saw Dr. Nichter. At this point, she was having dizzy episodes where she would see black spots and fall to the floor. Id. at ¶ 29. She also had tachycardia. Id. On October 21, 2009, she saw Dr. Sandler again[5] for sleeping issues. Id. at ¶ 30. He prescribed Ambien, which resulted in her having severe disorientation and hallucinations. Dr. Sandler then prescribed Trazadone, but she did not take it for fear of side effects. Id. On November 6, 2009, she saw Dr. Charles Rheeman, a neuro-ophthalmologist, for her difficulties in reading but he thought that stress was causing those problems. She became very upset "because I knew I was suffering from something that was real and the doctor's opinion seemed to dismiss everything I had been going through." Id. at ¶ 33. On March 1, 2010, petitioner saw Dr. Nichter who questioned the diagnosis of POTS and petitioner's being treated with steroids. Id. at ¶ 41. Petitioner states she continues to have difficulty reading. Id. at ¶¶ 50, 51.

On June 22, 2015, petitioner filed additional medical records. Exs. 573, 574. On that same date, respondent filed the supplemental expert report of Dr. J. Lindsay Whitton, discussing and disagreeing with Dr. Shoenfeld's ASIA theory. Ex. BBBBBB.

On June 24, 2015, petitioner filed additional medical records. Ex. 575.

From July 13-15, 2015, the undersigned held a hearing in this case. Petitioner provided additional exhibits in this case, which were marked as exhibits 577 and 578 with a color version of exhibit 576.

On July 21, 2015, respondent filed Ex. AAAAAAA (or for easier reading, Ex. 7A), consisting of a medical history, dated August 1, 2010, which petitioner's father prepared and from which he testified. Petitioner's father notes that petitioner's first post-vaccination headache occurred on February 20, 2009, which was five days after she had a severe sore throat, fatigue, a low-grade temperature, and swollen glands, but 11 weeks and two days after her second Gardasil vaccination, administered on December 3, 2008. Ex. 7A, at 1. He dates her inability to walk to March 2, 2009, or 12 weeks (three months) after her second Gardasil vaccination, describing her inability as an inability to find balance to walk, although never any true vertigo or nystagmus. She would just seem to collapse onto the floor. She would describe her legs as just going weak.

[5] Petitioner has not filed the medical record reflecting her visit to Dr. Sandler for sleeping issues.

Her pain was now 10++ and she was crying throughout the day and night. Id. He notes that on May 28, 2009, petitioner had increased lower extremity weakness and her headaches were still problematic. Dr. Nichter described her gait as abasia/astasia. Id. at 2. Petitioner began physical therapy with Adrian Fil on July 14, 2009. Id. at 3. Petitioner had brain MRIs on March 18, 2009 and June 9, 2009. Both were normal. Id. at 2, 3. She had an EMG nerve conduction study on July 20, 2009, the results of which were normal. Id. at 3. Petitioner's father notes that school began on September 10, 2009. Petitioner tried to make it at school with assistance, but the crowds, noise, and light became too much. Her headaches worsened even though she had improved over the summer in her walking and gait. Id. Petitioner's father notes that petitioner's passing out episodes became problematic. She said she saw black spots and then fell to the floor. She had tachycardia. Physical therapy was deemed imperative. Id. Petitioner's father notes that petitioner saw Dr. Sandler for help with sleep problems, and he prescribed Ambien. Petitioner had severe disorientation and hallucinations that night, including seeing the death of her brother. Dr. Sandler then recommended Trazadone, but petitioner was reluctant to take it because of her experience with Ambien. Id. at 4.

Petitioner's father notes that petitioner saw Dr. Charles Rheeman a neuro-ophthalmologist because of her difficulty reading. Petitioner's father notes that the office was tiny with people and staff everywhere. Dr. Rheeman found petitioner normal after examination and suggested that stressors were the root of her problem. Petitioner's father writes that petitioner promptly told Dr. Rheeman off. Id. Petitioner's father notes that, from late March to late April 2010, petitioner had a period of gradual good improvement. Id. at 5. Her headaches were 3/10. Her school time increased to several hours each morning. She began to play the flute again. She had been released from physical therapy, but stamina and fatigue were still problematic. She enjoyed herself on a cruise during Easter break, but had times of needing to crash. Id. Petitioner's father notes that, beginning in late April 2010 through May, she had severe worsening with headaches of "40"/10, according to petitioner. Id. On May 5 and 6, 2010, petitioner's father e-mailed petitioner's story to Dr. Julian Stewart, a pediatric electrophysiologist at Westchester Medical Center. He replied that petitioner's blood pressure that low while supine was not part of POTS at all. He said that even hypotension while upright is not part of POTs, although late during a tilt-table test, there are gradual vasodepressor responses. Dr. Stewart inquired whether petitioner had been checked for Addison's and for any other symptoms of autonomic failure. Id. (Dr. Stewart's e-mail response is not part of the record.) Petitioner's father notes that, on July 29, 2010, after a consultation with Dr. Jill Abelseth, an endocrinologist, a Cortrosyn[6] stimulation test for adrenocorticotropic hormone ("ACTH") was done, and the result was normal. Id. at 6. Petitioner's father notes that petitioner saw Dr. Peter Rowe, a pediatrician, at Johns Hopkins, who felt petitioner had chronic fatigue

[6] Cortrosyn is "trademark for a preparation of cosyntropin." Dorland's at 422. Cosyntropin is "a synthetic polypeptide identical with the first 24 amino acids of corticotropin, having the corticotropic activity of corticotropin but lacking its allergenicity; used in the diagnosis of adrenal insufficiency by plasma corticol response following subcutaneous, intramuscular, or intravenous injection." Dorland's at 424.

syndrome. Id. Petitioner's father notes that from September 2010 to June 2011, petitioner was back to school full time and missed only two weeks in total. He states she easily fatigued and always had a headache. Her school absences were related to fatigue or headache worsening. Id. Petitioner's father's chronology ends after June 2011.

On October 28, 2015, petitioner filed her posthearing brief.

On February 1, 2016, respondent filed her posthearing brief.

FACTS

Pre-vaccination Records

Petitioner was born on February 2, 1994.

On April 5, 2004, petitioner went to her pediatrician, Dr. Karen M. Kennette at Pondview Pediatrics, complaining of having a cold for two and one-half weeks. Med. recs. Ex. 575, at 1. She still had a low-grade fever and was sleeping nonstop. Her father was worried because she had been sleeping a lot since she had a strep throat possibly in December. Id. On physical examination, petitioner's tympanic membranes were congested, her nose had copious drainage, and her throat was beefy red with a thick post-nasal drip. Her nasal mucosa were inflamed with the left nostril completely occluded. Id. A quick strep test was negative. Dr. Kennette diagnosed petitioner with pharyngitis/sinusitis and prescribed Flonase, albuterol inhaler, and Zithromax. Id.

Also on April 5, 2004, petitioner's Epstein-Barr virus ("EBV") nuclear antigen[7] was weakly positive at 1:10. Med. recs. Ex. 8, at 16.

On March 14, 2005, petitioner saw Dr. Richard L. Uhl, an orthopedist, for a fracture to her left ring finger. Med. recs. Ex. 14, at 1.

On April 4, 2005, petitioner returned to Dr. Uhl, complaining her ring finger was still tender and painful. Id. at 2.

On April 29, 2005, petitioner returned to Dr. Uhl. Her finger fracture completely healed. Id. at 3.

On October 24, 2005, petitioner went to Dr. Uhl with a right heel injury. The x-rays did not show any abnormalities. Id. at 4.

[7] Nuclear antigens are "the components of cell nuclei with which antinuclear antibodies [ANA] . . . react." Dorland's at 105. "Antinuclear" is destructive to or reactive with components of the cell nucleus, as antinuclear antibody." Id. at 108.

On April 6, 2006, petitioner went to Dr. Uhl, complaining of a right ankle injury, which he diagnosed as a fracture. He recommended a short leg cast. Id. at 5.

On April 17, 2006, Dr. Uhl switched petitioner into an equalizer boot. The x-rays showed no displacement. Id. at 6.

On April 25, 2006, petitioner saw Dr. Uhl on an urgent basis because of a new injury to her right lower extremity. Id. at 7. She gave a history that her leg fell through a beach chair and she hit her ankle. She had increased pain in her foot, ankle, and knee. She said her knee was bruised. Dr. Uhl evaluated petitioner's knee and found it was not particularly bruised or tender. The ankle was slightly tender. X-rays showed absolutely no displacement from the initial films. Dr. Uhl suspected this was a contusion. Id.

On May 6, 2006, petitioner saw Dr. Uhl, complaining of pain in her foot, which was slowly improving. Id. at 8.

On June 26, 2006, petitioner saw Dr. John A. DiPreta, another orthopedist with the same group as Dr. Uhl. Id. at 9. He said petitioner had a history of recurrent ankle injuries. Petitioner and her mother felt she had not really gotten any better and the ankle was not quite right. She had pain in various parts of her ankle since her injury. Petitioner had another injury on June 25, 2006 after getting out of the pool when her ankle gave out. She had sharp, shooting pains. Petitioner and her mother were quite frustrated because they felt this interfered with petitioner's ability to participate in activities. On physical examination, her sensory exam was normal. The range of motion of her ankle, hindfoot, and midfoot were within normal limits. Strength measured 4+/5. X-rays were unremarkable. Dr. DiPreta's impression was petitioner had right ankle pain. He questioned whether petitioner had some sort of deconditioning and would benefit from physical therapy. Id.

On March 30, 2007, petitioner saw Dr. Uhl for pain to the end of her right thumb. Id. at 10. X-rays were negative for fracture and the thumb did not droop. Id.

On June 6, 2007, when petitioner was 13 years old, she went to Pond View Pediatrics, complaining that, for the prior six days, she had had severe headaches, great sensitivity to light, and dizziness. Med. recs. Ex. 12, at 16 (same record at Ex. 574, at 3). She said she felt as if she were on a boat. Id. She was afebrile and did not have cold symptoms. Id. When she stood up, she felt very dizzy. Id. Dr. Kennette examined petitioner in a dark room where petitioner was wearing dark sunglasses. Id. Petitioner's gait was slightly slow secondary to her headaches. Id. The doctor's differential diagnosis was migraine,[8] Lyme disease, and viral meningitis. Id.

[8] Migraine is "an often familial symptom complex of periodic attacks of vascular headache, usually temporal and unilateral in onset, commonly associated with irritability, nausea, vomiting, constipation or diarrhea, and often photophobia. Attacks are preceded by constriction of the cranial arteries, often with

On June 7, 2007, petitioner's father called Dr. Kennette to say that petitioner still had a severe headache. Med. rec. Ex. 12, at 17 (same record at Ex. 574, at 6). On June 7, 2007, because of petitioner's headaches, she underwent a brain MRI. Med. recs. Ex. 552, at 46 (same record at Ex. 574, at 1). It was normal. Id.

On June 8, 2007, petitioner's mother called the pediatrician to say that petitioner was still complaining of a headache. Med. recs. Ex. 12, at 18. It was absolutely no better. Petitioner was taking her medicines and resting. She had to lie in a dark room. The mother said petitioner's brain MRI was negative and she wanted to know what else could be done. Petitioner's mother was very upset. Id. The pediatrician's staff telephoned petitioner's mother to take petitioner to Albany Medical Center emergency room since her pain was no better. Id. Petitioner could get a neurologist to check her there and obtain IVIG medications. Id.

On June 8, 2007, petitioner went to Albany Medical Center Emergency Department at the suggestion of her pediatrician. Med. recs. Ex. 1, at 1. Dr. Noah White examined her and took a history that she had an episode three weeks earlier while refereeing a children's soccer match in which she felt as if her head were spinning, and she had some headache associated with that feeling. Id. She had had to sit down. Id. This episode resolved within 24 hours. Id. Petitioner said she had been fine until about one week previously when she again developed a headache similar to the previous headache. Id. It was bilateral and frontal. Id. She had only a mild amount of dizziness. Id. She also had photophobia, phonophobia, and associated nausea. Id. She saw her primary care physician, who recommended she have a neurology consult. Id. She had some associated nausea, but no vomiting. Id. In addition, petitioner had been at the Emergency Department on June 7, 2007 for the same problem, during which she participated in tests, including a brain MRI. The test results were normal, except for a complete blood count, which had an elevated white count of 10,600. Id. On physical examination, petitioner was sitting in a darkened room and appeared to have a mild amount of discomfort. Id. Dr. White diagnosed petitioner with migrainous headache, prescribed Compazine, and recommended she have a neurologic consultation. Id. at 2. The neurologist on call was Dr. Jerome Haller, a pediatric neurologist, who saw petitioner and agreed she had migrainous-type headache. Id. Dr. Haller believed her history suggested she had a basilar migraine three weeks earlier, and prescribed Imitrex with a follow up with a neurologist in six to eight weeks. Id. After the administration of Compazine and Benadryl, petitioner said her headache had significantly improved to a 2/10 from a prior 6/10. Id. The final diagnosis was migraine. Id. Dr. White also discussed the case with Dr. Chame Blackburn, an emergency medicine physician. Id. at 2, 3.

On June 20, 2007, petitioner saw Dr. Uhl, complaining of reinjuring her right ankle. Med. recs. Ex. 14, at 11. X-rays were normal. Id.

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resultant prodromal sensory (especially ocular) symptoms . . .; the migraines themselves commence with the vasodilation that follows. Two primary types are distinguished [migraines with aura and migraines without aura]; the variety without an aura is more common." Dorland's at 1166.

On August 14, 2007, petitioner complained to her pediatrician of being tired when she was walking while on a trip with her family. It was unclear what was the etiology for her fatigue when she was walking. Dr. Kennette told her to keep a log. Med. recs. Ex. 12, at 11 (same record at Ex. 574, at 2.)

On December 10, 2007, petitioner saw Dr. Uhl, complaining of injuring her right ankle again. Med. recs. Ex. 14, at 12. Dr. Uhl suspected a ligament sprain. Id.

On January 9, 2008, petitioner saw Dr. Uhl, who noted she was improving following her sixth ankle sprain. Id. at 13. She needed to go to physical therapy. Id.

On March 14, 2008, petitioner saw Dr. Uhl with an injured left thumb. Id. at 14. This appeared to be a sesamoid fracture. Id.

On March 25, 2008, petitioner returned to Dr. Uhl, complaining that the cast was bothering her and that she had pain in her thumb. Id. at 15. Dr. Uhl removed the cast. New x-rays showed the alignment maintained. All splints tried on petitioner were uncomfortable. They settled on a particular splint. Id.

On March 26, 2008, petitioner's mother called Dr. Uhl and said petitioner's thumb was discolored and quite cool. Id. at 16. They came in and Dr. Uhl removed the splint. He made a new splint molded around the thumb, which she seemed to tolerate much better. He discussed the possibility of a regional pain syndrome. Id.

On April 2, 2008, petitioner returned to Dr. Uhl with her left thumb looking better. Id. at 17. However, petitioner complained that her pain persisted and she held her hand in a flexed position. Dr. Uhl recommended petitioner start Neurontin 100 mg. in the evening for nerve-related pain. Id. Petitioner complained of numbness and tingling throughout the thumb. Id.

On April 14, 2008, petitioner returned to Dr. Uhl saying she was no better, but her thumb in fact looked better. Id. at 18. Her hand was moving better. Dr. Uhl wanted to increase her Neurontin to twice a day. Id.

On May 5, 2008, petitioner returned to Dr. Uhl, looking somewhat better. Id. at 19.

On June 9, 2008, petitioner returned to Dr. Uhl, having made minimal progress. Id. at 20. She was unable to move her thumb particularly well. She had spasms when attempting to do so. Her hand was not particularly swollen. Dr. Uhl suspected petitioner had a complex regional pain syndrome in addition to her microtrabecular fractures. Id.

On June 30, 2008, petitioner returned to Dr. Uhl, having reinjured her left thumb. Id. at 22. X-rays were negative. Id. He thought she should look for other causes of her discomfort. Id.

Post-vaccination Records

On August 26, 2008, petitioner received her first Gardasil vaccination. Med. recs. Ex. 13, at 3.

On September 2, 2008, petitioner returned to Dr. Uhl with an injury to her left ankle. Med. recs. Ex. 14, at 23. X-rays showed a non-displaced fracture. Her left thumb was doing much better. Id.

On September 8, 2008, petitioner saw Dr. Uhl for a left distal fibula fracture. Id. at 25. She was having problems with the cast rubbing her big toe. Dr. Uhl did not even see a fracture on x-ray. But he thought she did have one. Id.

On September 22, 2008, petitioner returned to Dr. Uhl. Her left ankle fracture was healing slowly. Id. at 24.

On October 8, 2008, petitioner saw Dr. Uhl, having reinjured her left ankle. Id. at 26. X-rays did not show any specific abnormalities. Id.

On December 3, 2008, petitioner received her second Gardasil vaccination. Med. recs. Ex. 13, at 3.

On February 26, 2009, two and three-quarters months after vaccination, petitioner went to Pond View Pediatrics to see her pediatrician Dr. Kennette, complaining of a bad headache she had since February 21, 2009, of feeling not good, and having weak pain, cold symptoms, nausea, fever, dizziness, and photophobia. Med. recs. Ex. 12, at 26. That morning, she took two Advil and drank ginger ale without any change in her headache. Id. She had been on Cipro[9] since the prior Thursday. Id. Her father, a physician, wrote the prescription for Cipro for presumed sinusitis. Id. The pediatrician diagnosed petitioner with photophobia, bitemporal squeezing

[9] Cipro is the trademark name "for preparations of ciprofloxacin hydrochloride." Dorland's at 362. Ciprofloxacin is "a fluoroquinolone antibacterial effective against many gram-positive and gram-negative bacteria. . . ." Id. Some of the possible side effects of Cipro are: headache with chest pain and severe dizziness; fainting; fast or pounding heartbeats; muscle pain or weakness; being more sensitive to temperature, light touch, or the sense of body position; changes in mood or behavior, including depression, confusion, hallucinations, paranoia, tremors, feeling restless or anxious, unusual thoughts or behavior, insomnia, and nightmares; increased pressure inside the skull, including severe headaches, ringing in the ears, vision problems, and pain behind the eyes; severe skin reaction, including a red or purple skin rash that spreads; and nausea, vomiting, and diarrhea. https://www.drugs.com/ciprofloxacin.html (last visited: January 7, 2017).

pain, and migraine. Id. Petitioner walked out of the doctor's office holding onto her mother's arm. Id. The physician presumed petitioner had sinusitis. Id.

On March 1, 2009, at 8:30 p.m., the pediatrician's office notes a telephone call regarding petitioner. Id. at 27. Petitioner had had a headache for one week and saw Dr. Kennette, who gave her Lortab and Imitrex and petitioner got some relief, but she was crying in pain and nauseated. Id. She did not vomit, but had photophobia. Id. Petitioner was advised to try two tablets of Lortab and see if they helped. Id. If petitioner did not have relief, she was told to go to the emergency room. Id.

On March 2, 2009, at 10:40 a.m., the pediatrician's office notes a telephone call regarding petitioner. Id. Petitioner did not go to the emergency room. She took the Lortab and in six to seven hours after she used ice, she seemed a little better. Id. Petitioner just woke up about 20 minutes earlier. She still had a headache but it was not as bad. She had no other symptoms and was not ill. Id. Petitioner could move her head and neck fine. Her mother would watch her that day. If she got worse, she was to call back for an appointment that day. If she woke on the following morning and still had a headache, she should call for an appointment that day. Id.

On March 3, 2009, petitioner's EBV nuclear antigen was weakly positive at 1:10.[10] Med. recs. Ex. 8, at 16.

On March 6, 2009, petitioner went to the Albany Medical Center Emergency Department where she saw Dr. Joshua J. Hurwitz, who admitted her as an in-patient. Med. recs. Ex. 1, at 4. Petitioner said she had two and one-half weeks of migraine headache pain (putting onset in the third week of February 2009, or two and three-quarters months after the second Gardasil vaccination.) Id. She complained of alternating symptoms of pressure, stabbing, multilocational pain, bitemporal pressure, vertigo, nausea and vomiting with low-grade fever. Id. She stated she had had one previous episode like this in July 2008 (one month before her first Gardasil vaccination) when she had a couple of weeks of headache pain, which the doctors diagnosed as migraine after a normal brain MRI. Id. One new symptom was retro-orbital pressure and ataxia. Id. She felt as if the room were spinning. Id. Her pediatrician was Dr. Karen Kennette. Id. Over the prior couple of weeks, she had tried Percocet, Imitrex, NSAIDs, Benadryl, Compazine, Depakene, and Antivert. Id. None of these medications addressed her pain. Id. On physical examination, petitioner had a negative Romberg sign[11] yet she appeared to overcorrect with loss of balance. Id. at 5. Her gait was narrow-based, but ataxic with petitioner requiring assistance in order to ambulate without falling. Id.

[10] This was the same result as on April 5, 2004 (pre-vaccination). Med. recs. Ex. 8, at 16.

[11] The Romberg sign is "swaying of the body or falling when standing with the feet close together and the eyes closed; the result of loss of joint position sense, seen in tabes dorsalis and other diseases affecting the posterior columns." Dorland's at 1715.

On March 6, 2009, on recommendation from Dr. Hurwitz, petitioner saw Dr. Charles Nichter, a pediatric neurologist. Id. at 7. He took a history from petitioner and her parents. Id. Unlike the history petitioner gave Dr. Hurwitz in the Emergency Department, petitioner told Dr. Nichter that there was no clear nausea or vomiting with her headaches. Id. She also told him that, two years previously (2007), she had a similar event, which was brief. Id. Petitioner's family history was positive for multiple sclerosis. Id. On physical examination, petitioner had a normal gait. Id. at 8. She did tandem gait with "an ever so slight wobble." Id. She hopped on one foot and two feet. Id. She squatted without difficulty. Id. Dr. Nichter assessed petitioner as having headaches and dizziness. Id. He felt she did not have concerning ataxia or vertigo. Id. She also did not have nystagmus. Id. He felt her variety of medications might have been exacerbating her headaches. Id. Dr. Nichter prescribed Reglan and then Depacon. Id. In future, he would decide whether to prescribe Depakote or Topamax. Id.

On March 8, 2009, petitioner's father telephoned the staff physician to report that petitioner had a good day March 7, 2009, but on March 8, 2009, she had a headache of 9/10 and difficulty sleeping the prior night. Id. at 11. She could walk with a little assistance. Id.

On March 13, 2009, Dr. Kennette wrote a letter to petitioner's high school, explaining that petitioner had been unable to attend school for the prior two to three weeks due to severe daily headaches. Petitioner had been unable to sit, stand, or concentrate long enough to attend classes. Id. at 33.

On March 16, 2009, petitioner's mother telephoned Dr. Nichter to say that petitioner was a little better, had less headache, and functioned better. Med. recs. Ex. 1, at 12. Petitioner went walking for half a block the day before. Id. She had some dizziness and a sense of spinning. Id. She was able to get out of bed and went to school for half a day the prior week. Id. Dr. Nichter advised increasing petitioner's vitamin B2 and continuing on multivitamins with B complexes and magnesium. Id. She was to continue on Topamax. Id.

On March 18, 2009, petitioner underwent a brain MRI because of her migraine headaches. Med. recs. Ex. 552, at 45. The MRI was normal. Id.

On March 26, 2009, Dr. Nichter saw petitioner with her parents as a follow up visit to his initial visit with her in the Emergency Room on March 6, 2009 for migraines. Med. recs. Ex. 553, at 115. Petitioner gave Dr. Nichter a history that she had a sore throat after receiving Gardasil vaccine, and then, a week or two afterwards, had significant migraine headaches. Id. at 116. Since the emergency room visit, petitioner's mother states petitioner was better. Id. Her headaches started at 2-3/10 in the morning. Id. By the afternoon, they might increase to 4-5/10, and by evening, 8/10. Id. She did not have stabbing, sharp pains. Id. The headaches were more throbbing and pressure-like. Id. She had significant photophobia and significant vertigo. Id. Overall she was minimally to mildly better. Id. Petitioner's headaches, vertigo, and photophobia made her dysfunctional even when she wore sunglasses. Id. Petitioner did not have frank weakness, but rather just unsteadiness. She did not have marked lethargy or unresponsiveness.

She did not have any activity to suggest seizures. There was a family history of multiple sclerosis, but no headaches. Her brain MRI, MRA, and MRV were unremarkable. Id. On physical examination, she had no focal weakness. She could hop on one foot and two feet, but required support from a table or a chair. Id. at 117. She could walk 10 feet, but often sought her mother's support. Id. Dr. Nichter's assessment was that her significant migraine might relate to Gardasil, "although there is no clear literature to support that." Id. His plan was to increase petitioner's vitamin B2 and her Topamax dosage. Id. He considered steroids (Decadron or prednisone) in the future. Id.

On March 31, 2009, Dr. Kennette's office received a telephone call from petitioner's mother. Med. recs. Ex. 12, at 35. Petitioner's mother wanted the lot number of the Gardasil that petitioner had received. She said that petitioner's headaches had been ongoing since petitioner received Gardasil. In addition, a friend had received the same lot number of Gardasil and she had the same problem as petitioner. Id.

Also on March 31, 2009, Dr. Kennette filled out a VAERS (Vaccine Adverse Event Reporting System) form, writing that petitioner received Gardasil on December 3, 2008 and the onset of her vaccine reaction on February 21, 2009 or eleven weeks and three days later. Med. recs. Ex. 12, at 34. The only adverse event Dr. Kennette described was protracted headache. Id. Dr. Kennette states on the VAERS form that petitioner recovered. Id.

On April 6, 2009, petitioner and her parents saw Dr. Nichter again. Med. recs. Ex. 1, at 16. She had slight improvement, but on Thursday night and Friday, she was working on a school project and sleep was difficult. Id. On Friday, her headaches were 9/10 to 10/10, bitemporal, and crushing, associated with photophobia, and phonophobia. Id. She did not vomit, but her appetite had significantly decreased, and she had lost four pounds. Id. She swayed from side to side and, sometimes, her legs felt like jello with her knees about to give out. Id. Sometimes, the fragrance of foods nauseated her. Id. On physical examination, petitioner could sit but tended to lean. Id. at 17. When she walked, she leaned along furniture without frank ataxia, but with a leaning on objects kind of gait. Id. She could not stand independently. Id. Dr. Nichter assessed petitioner as having minimally improved migraine, and a wobbly gait although not formally vertigo (she said nothing was spinning or tilting), and no clear ataxia. Id.

Also on April 6, 2009, petitioner's ANA was 1:640 with an atypical discrete speckled pattern. Med. recs. Ex. 1, at 19.

On April 13, 2009, petitioner and her parents saw Dr. Nichter again. Med. recs. Ex. 1, at 19. She had significant photophobia, but her blurred vision resolved. Id. She had a slight improvement in appetite. Id. Besides her headaches, her gait was of concern. Id. Her legs seemed to her as if they were going to give in. Id. At times, she had more of a slither to the ground than a frank direct fall from a standing position. Id. She had a little left neck tenderness that appeared mild. Id. After a physical examination, Dr. Nichter wrote her migraines had

improved, petitioner had minimal to no vertigo and minimal to no ataxia. Id. at 20. She had a wobbly gait, without evidence of posterior column dysfunction. Id.

On April 22, 2009, Dr. Kennette's office called petitioner's mother. Med. recs. Ex. 12, at 37. Petitioner still had daily headaches, which were worse at night, and felt that her legs were not part of her body. She was unable to walk without holding onto objects. She had been unable to attend school for the past month. There was a lot of stress at home since petitioner's maternal grandmother died on March 22, 2009 and petitioner's father had surgery during the past month. Id. Petitioner's father was meeting with Dr. Sarah Elmendorf and would like Dr. Kennette to call him. Id. Dr. Kennette's office notes on April 23, 2009 that there were telephone calls over the prior 24 hours with petitioner's mother, father, and Dr. Elmendorf. Id. at 39. Petitioner was not improving at all. She had headaches, weakness, poor appetite, and had lost some weight. Id.

On April 23, 2009, petitioner's mother phoned Dr. Kennette's office. Id. at 38. She wanted the vaccination dates and lot numbers for the Gardasil petitioner received and the name of who administered the vaccination. This information had been previously sent to petitioner's mother, but she misplaced it and needed it immediately because she, her husband, and petitioner were going to Boston and putting together a log of events. In addition, she wanted the dates of petitioner's visits for headaches. Dr. Kennette's assistant started with June 2007. Id.

On April 24, 2009, petitioner's father called, concerned that petitioner now complained of muscle pains and had Theraband for home exercises. Id. at 40. There was a question whether her symptoms represented a myositis syndrome or if she had conversion syndrome because of astasia-abasia. Id.

On April 28, 2009, petitioner's mother called Dr. Kennette's office. Id. at 41. Petitioner was getting worse. Dr. Kennette was supposed to be setting up a visit to a doctor in Boston. Petitioner's father wanted to speak to Dr. Kennette. Id.

On May 1, 2009, petitioner visited Dr. Kennette for a reevaluation of her "weakness" (which Dr. Kennette put in quotation marks) and headaches. Id. at 42. Petitioner had not been in school for two months and was unable to walk or stand from a sitting position without assistance. Her feet felt cold and she weighed 116.5 that day. Petitioner walked down the hall hugging the wall. She sat in a dark room with sunglasses on. When she sat on the examination table, she leaned against the wall. Her muscle tone had decreased. The strength in her lower extremities seemed to be 4+ to 5 out of a maximum of 5. Her deep tendon reflexes in her lower extremities were difficult to elicit. Petitioner's mood was depressed but her orientation normal. She felt tired, sad, and frustrated. She had normal skin temperature and color over her feet and hands. She was wearing a T-shirt, sweatshirt, and heavy sweat pants. The outside temperature was about 65 degrees. Petitioner had protracted inability to walk without support, a persistent "migraine"-like headache (Dr. Kennette put "migraine" in quotation marks), mild anorexia, an eight-pound weight loss over 8-10 months, and mild depression. She questioned whether petitioner had an undiagnosed neuromuscular condition. Id.

On May 4, 2009, petitioner saw Dr. Magdi Sobeih, a behavioral neurologist, at Children's Hospital in Boston. Med. recs. Ex. 2, at 1. Dr. Sobeih saw petitioner to evaluate her headache and walking difficulties. "After a thorough evaluation I have concluded that there are no neurobiological abnormalities or neuropathological concerns to [petitioner]'s complaints." Id. Dr. Sobeith recommended petitioner participate in therapy and take Elavil. He did not recommend that she have any further neurological workup but follow up with her primary physician. The history petitioner's parents gave was that during February break, petitioner complained of a sore throat and was ill for one week. On Monday, she went to school but the school sent her home because she was feeling ill. On Tuesday, she went back to school and complained of headaches with a stabbing type of pain all around, more on the right side. She described it as vise-like, which then progressed to a pressure-like headache. She stated it felt as if someone were dropping an anvil on it. She described pressure all around her head. None of the therapeutic interventions made any difference. Loud noise or attempts to read made her headaches worse. Her appetite decreased and she lost ten pounds. Certain smells bothered her. She complained of dizziness. She felt unsteady and needed to lean on a wall. This resulted in her inability to ambulate effectively. She tended to slide along a wall. "There has been some suggestion of temporal association according to the family with [petitioner] having received the HPV vaccine and then subsequently had the sore throat and a week later having headaches." Id. Because of her headaches, her doctor started her on Topamax, vitamin B2, magnesium, a multivitamin, and Ibuprofen. None made any difference to her headache in any way. Id. at 2. The most recent symptoms had been difficulty in ambulation. She felt as if she were swaying from side to side and her legs and knees were going to give out. She had to lean on a wall in order to get up or to walk. She also wore dark glasses because light bothered her eyes. She was unable to attend school for many weeks and had a home tutor. All of petitioner's lab work was negative. She had negative Lyme titers, negative Epstein-Barr virus titers, and a normal C-reactive protein of 0.2. Dr. Sobeih believed petitioner's antinuclear antibody of 1:640 with an atypical discrete speckled pattern was probably a false positive. Her sedimentation rate was eight, which is normal. Id. Her DNA antibody was negative for double-stranded DNA. Id. at 2-3. Her brain MRI, MRA, and MRV were normal. Id. at 3. On physical examination, petitioner could not bear weight on her legs and walk. She complained of photophobia and covered her eyes. On gait testing, petitioner had a significant amount of astasia-abasia.[12] She had a

[12] Abasia-astasia or astasia-abasia is "motor incoordination with an inability to stand or walk despite normal ability to move the lower limbs when sitting or lying down, a form of hysterical ataxia." Dorland's at 167. Hysterical ataxia is "ataxia that is part of a conversion disorder." Id. at 171. Ataxia is "failure of muscular coordination; irregularity of muscular action." Id. at 170. Conversion disorder is "a mental disorder characterized by conversion symptoms (loss or alteration of voluntary motor or sensory functioning suggesting physical illness, such as seizures, paralysis, dyskinesia, anesthesia, blindness, or aphonia) having no demonstrable physiological basis and whose psychological basis is suggested by (1) exacerbation of symptoms at times of psychological stress, (2) relief from tension or inner conflicts (primary gain) provided by the symptoms, or (3) secondary gains (support, attention, avoidance of unpleasant responsibilities) provided by the symptoms. . . . [H]istrionic personality traits are also common. Symptoms are neither intentionally produced nor feigned. . . ." Id. at 549. "Histrionic" is

completely functional[13] gait without weakness. Sensory examination and coordination were normal. She did not have dysmetria or ataxia. Dr. Sobeih wrote:

> I had a long discussion with the parents that there is no neuropathological finding. There is no focality on neurological exam; there is no neurological cause for [petitioner]'s symptoms. This did present as a functional gait disturbance.

Id. Dr. Sobeih recommended that petitioner have ongoing counseling. He stated, "I do not feel there is any association between the Gardasil HPV vaccine and the onset of these symptoms." Id. He continued:

> I discussed this at length with the parents. I discussed that this is presenting as a mood disorder that needs appropriate care. . . . It would be very important to[o] that [petitioner] continue under the care of appropriate psychological or psychiatric services and someone to monitor her response to any medications such as amitriptyline. However I do not feel there is any need for any further neurological workup or followup. I discussed this with the parents and with [petitioner] and I counseled further mental health care should be provided.

Id. at 3-4.

On May 5, 2009, petitioner's mother called Dr. Kennette. Med. recs. Ex. 12, at 44. The consultant in Boston felt petitioner had nothing neurologically wrong with her, that she never had migraines, and was depressed. Id.

Also on May 5, 2009, Dr. Kennette filled out a child and adolescent psychiatric telephone consultation request to Four Winds Foundation, asking if a psychiatrist would see petitioner for conversion syndrome. Id. at 48. Petitioner had been seen in Boston where she received an assessment of "no neurological disease" and a question arose concerning whether petitioner were depressed and should have a trial antidepressant and therapeutic counseling. Id. The recommendation was to have petitioner's parents call for an appointment.

"excessively dramatic or emotional; of or relating to the behavioral characteristics of histrionic personality disorder." Id. at 864. Histrionic personality disorder is "a personality disorder marked by excessive emotionality and attention-seeking behavior." Id. at 550.

[13] A functional disorder is "a disorder of physiological function having no known organic basis. . . . [T]he term is often used in psychiatry as roughly equivalent to 'psychogenic disorder' . . . ." Dorland's at 550.

On May 6, 2009, petitioner's mother called Dr. Kennette. Id. at 45. Petitioner was going back to school. The school needed a note stating she could return and limit herself to part-time attendance. Petitioner would be in a wheelchair. Id.

On May 7, 2009, Dr. Kennette called petitioner's father to discuss where to go from there. Id.

On May 8, 2009, a nurse's note from Dr. Kennette's office states that petitioner was concerned because Boston doctors suggested a psychiatrist assess her. Id. at 47. Petitioner requested a meeting with Dr. Kennette to discuss this. In addition, when petitioner's mother brought the doctor's note to school, indicating petitioner would be coming back to school part-time, the mother ran into petitioner's former coach and gym teachers. While discussing petitioner, the coaches indicated that a lot of girl athletes seemed to be "sick" (the nurse used quotation marks around "sick") now and were unable to do sports. Petitioner's mother was obtaining a list of the girls' names from the teachers and coaches and was having the parents call her to see if these girls' sicknesses were associated with Gardasil. Id.

On May 8, 2009, Dr. Kennette met first with petitioner's parents and spoke to them for 20 minutes. Id. at 46. Then, Dr. Kennette met with petitioner and spoke to her for about an hour alone. They discussed how petitioner felt, what had and had not helped, the need for her to go back to school, strategies for coping with food, sound and light sensitivity, dealing with parental and friends' expectations, etc. Dr. Kennette emphasized that petitioner needed to go back to school, with or without a wheelchair, on a full-time basis. She needed to work with the gym and music teachers for alternative work, e.g., physical therapy sessions instead of gym, composition instead of playing in music class. Petitioner needed to check with her neurologist regarding her use of Topamax since it was not helping. Perhaps she should start a new medicine such as Elavil for headache and mood. She needed a positive outlook on improvement. Id.

On May 12, 2009, petitioner saw Dr. Jason Mouzakes, an ear, nose, and throat specialist, for a vestibular evaluation. Med. recs. Ex. 4, at 1. Petitioner was taking melatonin, multivitamins, Topamax, and Vitamin B-12. She complained of an eating disorder, migraine headaches, and vertigo. Petitioner gave a history that, over the prior three months, she had episodes of debilitating headache and dizziness, as well as photophobia, nausea, and phonophobia. She had tried several medications including Antivert and Depakene without improvement. She had a normal head MRI. All lab work, including Lyme titer, was normal. Id. Dr. Mouzakes wrote that petitioner's physical examination was reassuring. Id. at 2. He ordered that petitioner have an ENG study for further evaluation of her inner ear balance system. He also ordered an audiogram to evaluate her middle and inner ear findings. Since petitioner had missed more than three months of school, he would expedite the ENG testing. Id.

On May 13, 2009, petitioner had audiologic testing at the hearing center at Albany Medical Center Hospital. Id. at 3. Under "Complaint" is the note that onset of symptoms of dizziness and hypersensitivity to sounds and light was in February 2009 "correspond[ing] with

the administration of Gardasil vaccine" (although the vaccine was administered December 3, 2008). Id. Petitioner's hearing test results were normal bilaterally. She had normal middle ear function and normal outer hair cell function in the cochlea. Id.

On May 14, 2009, petitioner and her parents saw Dr. Nichter. Med. recs. Ex. 1, at 22. Since her last visit to Dr. Nichter, she had seen a pediatric neurologist in Boston who thought petitioner had a major psychological or psychiatric component to an ill-defined headache syndrome. Id. The Boston doctor was not convinced petitioner even had migraines. Id. Petitioner's mother said petitioner's headaches were better since Dr. Nichter first saw petitioner in the ER, but they were quite variable. Id. On May 13, 2009, petitioner underwent vestibular testing and she had a significant headache. Id. But, at other times, her headaches were better. Id. She still had photophobia and phonophobia. Id. Normal sounds were extremely loud and regular lights created major photophobia. Id. What Dr. Nichter found most pronounced was petitioner's abasia-astasia type gait (consistent with Dr. Sobeih's diagnosis). Id. She would lurch onto an arm or side of a chair or a wall. Id. At night, she would fall to the floor and sort of get up to go to the bathroom. Id. She stated it was difficult for her to concentrate even with a homebound school program for a few hours. Id. She was unable to walk, and had decreased appetite. Id. Smell or fragrance of food was problematic. Id. at 22-23. On physical examination, she bore weight but had swaying when she tried to walk. Id. at 23. However, when Dr. Nichter swayed in the opposite direction while walking with petitioner, petitioner seemed to adjust her swaying and, when he moved her arm in a different way, she also adjusted accordingly. Id. When Dr. Nichter tested her sensation, petitioner said "sharp" when he placed a dull object on her leg. Id. However, she was not consistent when he placed sharp and dull objects on the same area. Id. Dr. Nichter prescribed Elavil and suggested decreasing Topamax. Id.

On May 18, 2009, Dr. Kennette wrote a letter to petitioner's high school, requesting permission for petitioner to return to school on a graduated basis. Med. recs. Ex. 12, at 49. Petitioner was trying to regain strength and ambulation, but might need to use a wheelchair between classes and asked for accommodation for her to do so. In addition, Dr. Kennette asked the school to work with petitioner's family in obtaining any necessary academic support to make up work she missed, including tutoring. Id.

On May 22, 2009, Jamie Steck, a pediatric physical therapist, evaluated petitioner. Med. recs. Ex. 11, at 1. Petitioners' parents and neurologist, Dr. Nichter, referred petitioner for physical therapy because of parental ongoing concerns regarding her inability to walk independently, unstable standing balance, weakness, and decondition noted since she had a sore throat about three months earlier just prior to February School Vacation week. Id. A few days after the sore throat, she complained of headaches. On Friday of that vacation week, petitioner had significant sensitivity to light and sound, was exhausted, and complained of severe headache. She was given migraine medication, but had no change. She subsequently went to Albany Medical Center emergency room for severe headaches and was given a migraine cocktail combination, but reacted to the medicine. She had frantic, anxious behavior, which led to her

being seen by a neurologist. Dr. Nichter prescribed a multivitamin, Topomax, and Elavil. She continued to complain of headaches that were band-like on the lateral side of her head. Her headache symptoms increased with neck hyperextension and rotation motions. Boston Children's Hospital neurology also evaluated petitioner and petitioner's mother reported that the hospital thought her symptoms were psychological. Petitioner had a very limited diet due to sensitivity to smell and taste. She had lost 20 pounds since becoming ill. She had progressively greater difficulty with balance and standing and got weaker as time passed.

Petitioner also said she could not make her legs do what she wanted them to do and they felt as if they were going to give out on her. P-T Steck was concerned about petitioner's severely limited standing balance, inability to walk independently, decreased coordination, speed of her limb motion noted more in the left leg than in the right, and decreased positional sense of her left lower extremity. Dr. Mouzakes evaluated petitioner for vestibular problems, and ruled out vertigo. She had a negative MRI and a normal EEG. Previous neurological examinations did not reveal any neurologic involvement despite her inability to sustain balance independently or to coordinate independent gait. Petitioner's mother reported she had been "clutsy" as a child and often injured herself playing soccer. She fractured her left ankle in August 2008. Petitioner's mother wondered if petitioner's second Gardasil vaccination in December 2008 affected petitioner's current status. Petitioner's mother reported petitioner currently attended school two hours a day while sitting in a wheel chair, and was exhausted upon return home. Petitioner had been an A student and now had extreme difficulty reading and attending at school. Petitioner reported that, while reading, things became blurry and words moved on the page. She continued to have light sensitivity and her eyelids drooped over half of her eye throughout the evaluation. Petitioner presented with a low affect and tended to look in a downward gaze with her neck held in a forward flexed position with a slight rotation to the left. Despite being given verbal prompts to encourage eye contact or hold her head up, she continued to posture her neck down. During gross visual testing, petitioner was able to move her eyes in all directions, and P-T Steck noted petitioner's eyelid motion, but, at rest in sitting, her eyelids were lowered covering half of her eyes. Id. Petitioner reported having a very difficult time keeping up with her school work, and falling a lot at home. Id. Petitioner showed a decrease in the rate of her language output and a slow reaction time in answering questions. Id. at 2.

Petitioner had muscle tone on the low end of normal throughout her trunk and extremities. Id. When supported with maximum assistance in standing, petitioner laterally glided and pushed her weight dangerously toward the right in dystonic motion. She presented with ataxic arm and leg motions, especially in the left leg. During assisted standing, petitioner held her left leg abducted and externally rotated at her hip, with the knee in hyperextension. While attempting assisted steps, petitioner circumducted her left leg (circled her leg from the hip to generate swing phase), showed plantar flexion (foot drop), and then hyperextended her knee upon weight bearing with a flat foot placement that maintained her left ankle in a plantar flexed position. Id. Petitioner had generalized muscle weakness throughout her trunk and extremities due to deconditioning. During manual muscle testing, she had strength within functional limits through her trunk and extremities at a good minus grade with the exception of left ankle eversion

and supination control, which was fair. Petitioner was able to lie down and sit up on her own, but her movement showed decomposition, which was slow and mechanical like a puppet. She showed incoordination in all functional movement. Her grip strength was weak, but her writing skills remained intact. Id. P-T Steck recommended physical therapy three times a week. Id. at 4. She spoke with petitioner's neurologist and pediatrician, and her neurologist would see her again. Her symptoms and movement pattern were typical for cerebellar involvement. In addition, her limited diet and nutrition had an effect on her symptoms. P-T Steck recommended an ophthalmologist examine petitioner considering her visual concerns. She recommended home exercises.

On May 28, 2009, petitioner and her parents saw Dr. Nichter on an urgent basis for petitioner's weakness, gait disturbance, and migraine. Med. recs. Ex. 1, at 25. A physical therapist thought she had weakness in her left leg and foot drop. Petitioner's mother stated she did see a circumduction of petitioner's left leg at times although there was no catch at the left foot or stumbling. Petitioner would turn her left foot in at times. This was noticeable when petitioner had significant activity or a stressful day. There was no new weakness in her arm or weakness in her face. It was not clearly related to the severity of her migraines. There was no new ataxia. If there were a social event where music played, petitioner's headache would be quite severe. She used sunglasses a bit less now than previously. She had stopped Topamax and vitamin B2. Id. She was taking magnesium, multivitamins, and Elavil. Id. at 25-26. Physical examination showed full strength in her arms, but occasional give-away weakness in the quadriceps and hamstrings. Id. at 26. She had variable responses to position sense, but she was correct at least 75 to 85 percent of the time. Id. Vibratory sense was normal. Id. When petitioner walked, she still lurched to one side or the other. Id. At times, she would invert her left foot, but there was never a foot drop. Id. The foot inversion was intermittent, i.e., inconsistent. Id. Dr. Nichter assessed petitioner's migraines and photophobia as a little bit better. Id. Her gait remained in the abasia-astasia category. Id.

On June 7, 2009, petitioner had a brain MRI done because of her headaches. Med. recs. Ex. 574. Her brain MRI was negative. Id.

On June 25, 2009, petitioner saw Dr. Hilaire J. Meuwissen, an allergist and immunologist. Med. recs. Ex. 573, at 1. Petitioner's illness began approximately February 15, 2009 with a severe sore throat and fatigue, low-grade temperature, and swollen glands for about a week, about two months after she received her second Gardasil vaccination. Id. No doctor made a definite diagnosis after migraine therapy failed. Petitioner told Dr. Meuwissen that concentration was difficult and reading not easy because words moved back and forth and became larger and smaller haphazardly. Id. Petitioner walked close to the wall with support from the wall and reported she had many bruises from bumps and almost falling. Id. at 2. She looked pale and distressed and wore sunglasses because of extreme sensitivity to light. She was very sensitive on percussion of her frontal and maxillary sinus. Dr. Meuwissen's assessment was that petitioner might have a neurologic condition that her upper respiratory infection in February caused. Id. There was a remote possibility she might have a variant form of Guillain-Barré

syndrome secondary to Gardasil vaccination although the interval between vaccination and onset was long. Id.

On June 30, 2009, petitioner's antinuclear antibody ("ANA") was 1:640 in an atypical discrete speckled pattern. Med. recs. Ex. 8, at 17.

On July 6, 2009, petitioner and her parents saw Dr. Nichter. Med. recs. Ex. 1, at 28. Petitioner had undergone a brain MRI and MRA, both of which were normal. Her family said petitioner was 30 to 40 percent better. Her headaches were fewer, lasting an entire day or a few hours. She was able to walk more upright, although she still needed support. She could tolerate sunlight and her appetite was better. Her mood and disposition were better. She complained of belly pain twice a week. Id. On physical examination, her strength was 5/5 with occasional giveaway weakness. Id. at 29. She had less lurching gait. She took two to three steps on her own without leaning as much. There was no foot drop or involuntary movement. Dr. Nichter's assessment was that petitioner's migraines and abasia-astasia were both improving. Muscle strength testing was quite variable as she had giveaway weakness but sometimes she generated more force. Id.

On July 14, 2009, petitioner started physical therapy with Adrienne Fil at Sunnyview Rehabilitation Hospital. Med. recs. Ex. 11, at 6. According to Ms. Fil's record of August 13, 2009, after 14 P-T sessions, petitioner's "physical presentation with mobility continues to be incongruent with objective measurements." Id. at 8. Ms. Fil questioned the possibility of petitioner having a conversion disorder. Id. When Ms. Fil drew less focus to petitioner's impairments, petitioner had spontaneous improvement in her lower extremity function. Id. at 8-9. Petitioner's mother became concerned about petitioner continually blacking out and collapsing. Id. at 9. During the P-T session, petitioner was standing for at least 50 minutes of the hour-long session without difficulty while doing activities. Id. Ms. Fil was aware that petitioner was referred for a psych intervention earlier in her diagnosis and petitioner became physically worse. "Perhaps with her physically improving now she may be more open to counseling. . . ." Id. Ms. Fil mentioned this to petitioner's parents, but not to petitioner directly. Id.

On July 20, 2009, petitioner had a nerve conduction study ("NCS"), electromyography ("EMG"), and F Wave test done to determine if she had inflammatory neuropathy. Med. recs. Ex. 9, at 6. Dr. Matthew J. Murnane concluded the tests were normal without evidence of a peripheral neuropathy. Id. at 7.

On August 10, 2009, petitioner's father wrote Dr. David Cornbluth, stating that petitioner in February 2009 developed what seemed to be a viral illness two months after a Gardasil immunization. Med. recs. Ex. 3, at 3. This rapidly progressed to severe headaches, photophobia, phonophobia, complete loss of appetite, and a balance/gait disturbance. A multitude of testing was unrevealing. She had been out of school since February with home tutoring since then. She would sit in a dark, quiet room, unable to tolerate playing her flute, with no stamina for any

activity, although previously she had been an avid flute player and on the soccer and track teams. Standard migraine prescriptions were not helpful, including IV Depakote. Previously, petitioner was wheelchair-bound or wall walking only. Now she did some walking on her own. Petitioner's father asked if Dr. Cornbluth would be willing to see petitioner. Id.

On August 12, 2009, Dr. Kennette recorded petitioner's 15 year and six month old visit. Med. recs. Ex. 12, at 50. Petitioner was doing physical therapy at Sunnyview with Adrienne Fil at least three times a week since the end of June. Petitioner's nerve conduction and EMG studies were normal. Id. Petitioner's sensation was stronger on her right. She was currently taking Periactin, multivitamins, and Elavil. She had gained two pounds. Her blood pressure was 108/64. She weighed 113 and ¼ pounds. Her height was 5'5 and ¼ inches. Her BMI was 18, which put her in the 10-25% group. She was wearing sunglasses. She had cool, bluish feet. Her left calf was smaller than her right calf. Her proximate strength was 4+/5. Petitioner had ongoing issues with gait, headaches, photophobia, hyperacusis,[14] change in taste, and food aversion for five to six months. Id. There was no specific diagnosis made up to that date. Petitioner's parents were considering consulting with Dr. David Cornbluth in Baltimore. There was a follow up with the neurologist the following week. Perhaps petitioner should have a lumbar puncture. Id.

On August 17, 2009, petitioner and her parents saw Dr. Nichter. Med. recs. Ex. 1, at 31. Petitioner underwent EMG and nerve conduction studies, which were normal. Since Dr. Nichter last saw petitioner on July 6, 2009, she had had "enormous variability." Id. She could walk on a board, walk independently, and, on one occasion, walk a few miles. The headaches were variable, from mild to so severe she was weeping. She had photophobia and phonophobia. She had a significant decrease in appetite. Petitioner's father was researching vaccine-related individuals. Id. On physical examination, petitioner could walk and move from chair to standing. Id. at 32. She took several steps walking on her own and leaned on the side of the wall as she moved from the clinic to the checkout area. She did not have footdrop. There was an occasional inturning of her left foot. Id. Dr. Nichter's assessment was that petitioner was improving and her gait was significantly better. She was down to one severe headache a week. He increased her Elavil. He also recommended she do five sit-ups a day and continue physical therapy three times a week, one of which times was aquatherapy. Id.

On August 25, 2009, petitioner's parents met with Dr. Steven Sandler,[15] a pediatrician and psychiatrist at Albany Medical College, to find out if petitioner's multiple physical

[14] Hyperacusis is "exceptionally acute hearing; the hearing threshold being unusually low. It may or may not be accompanied by pain." Dorland's at 886.

[15] Dr. Steven Bruce Sandler was board-certified in psychiatry on October 30, 1990. This board certification is valid indefinitely. He was board-certified in child and adolescent psychiatry on November 11, 2000 through December 31, 2010, but his status as of January 23, 2017 was not board-certified in child and adolescent psychiatry. https://application.abpn.com/verifycert/verifyCert.asp?a=1&u=1# (last visited: Jan. 23, 2017).

symptoms were psychological in origin. Petitioner was not with her parents at this first conference with Dr. Sandler. Med. recs. Ex. 7, at 1. Petitioner's parents were concerned that Gardasil vaccination in December 2008 may have caused her whole problem. In February 2009, petitioner developed a viral illness with headache and malaise. She also developed photophobia, phonophobia, and annoyance with smells. After two or three weeks, she had a gait problem. A number of physicians saw her. Her strength and physical examinations were normal. Her testing was normal except for an elevated antinuclear antibody ("ANA"). A presumptive diagnosis was migraines. Petitioner became so incapacitated that she had been in a wheelchair and out of school since February. Petitioner seemed to be depressed and had lost weight, mostly because the smell, taste, and consistency of food troubled her. Id. A child neurologist at Boston Children's Hospital felt the cause might be psychological. A physical therapist, Adrian Fil, at Sunnyview Hospital, noted petitioner's sensitivity to sound and light as well as her gait had improved slightly, but Ms. Fil pointed out to petitioner's parents that petitioner's examination was inconsistent from one day to the next. Id. Petitioner was a high honors student, and remained a high honors student even while at home and studying with a home tutor. She had trouble reading and had to isolate one line at a time with an index card. Nevertheless, she read three books on her own in the summer. Id. Petitioner told her parents she did not want to go back to her high school because of the students and their reaction to her illness. Id. Petitioner took Imitrex, hydrocodone, Benadryl, intravenous Depakene, Maxalt, Compazine, and B vitamins for migraine headaches. She was currently on Amitriptyline, Periactin, and multivamins. Id. Petitioner had an older brother and a younger sister. Id. at 2.

On September 1, 2009, petitioner saw Dr. Sandler. Id. at 3. He notes: "She says it all began with a sore throat in February. Then, she developed flu symptoms, a headache, wobbliness, and a sense that the halls were spinning at school. The headache has persisted ever since. It is mostly bitemporal but sometimes she feels it at the back of her head too." The quality of the headache varied. Sometimes it felt like a knife, but at other times it pulsed or throbbed or felt like pressure. It never went away and varied from 2/10 to 10/10. She said she wanted to go back to school (the opposite of what petitioner's parents told Dr. Sandler on August 25, 2009). Id. at 3. Petitioner also had photophobia and phonophobia. Id. Petitioner told Dr. Sandler that she had a headache for a week in the seventh grade, which was diagnosed as a migraine and which resolved completely. Id. She also told Dr. Sandler that she was quite happy in February 2009 and had no particular stressors. Id. Besides her headache, and the annoyance of loud or high-pitched sounds and of light, petitioner said food tasted weird to her, being either too salty or too bitter. Id. Her appetite had declined and she had lost weight. Petitioner said she and her mother were best friends, but she had not seen much of her father growing up because he worked long hours as a physician. Petitioner denied depression (the opposite of what petitioner's parents told Dr. Sandler on August 25, 2009). She said she woke up a lot at night. Id.

Dr. Sandler noted that petitioner came to the office with the assistance of her mother because she was unstable walking on her own. However, she did walk unassisted as she left Dr. Sandler's office, but walked very slowly and not steadily. He noted she was alert, oriented, very cooperative with the interview, and made good eye contact. Her speech was clear and normal in

flow and volume. Her thought process was entirely normal and she appeared alert and oriented with normal intellectual capacities. Dr. Sandler summarized his impression. Petitioner's parents believed her symptoms since February 2009 were due to a Gardasil immunization. She sounded quite eager to go back to school and join her friends and activities. Dr. Sandler had "no suspicion that she is malingering[16] or trying to play a sick role." Id. He did not suspect her symptoms were psychosomatic.[17] She read several books that summer with great effort. Id. He offered her a session of hypnosis to alleviate her headache pain and she agreed to come back in a week to do that. Id. at 4. He concluded that petitioner did not seem to be suffering from significant anxiety or depression that might exacerbate her symptoms or worsen her perception of physical pain. Id.

What is noticeable about Dr. Sandler's opinion is he has no notation that he ever read petitioner's medical records including the physical examinations that other physicians performed on petitioner, or performed his own physical examination of her. (He could not have seen petitioner's father's summary of petitioner's medical records because petitioner's father did not create it until a year after this visit.[18]) Moreover, he never comments about the discrepancy between petitioner's parents' statements and petitioner's own statements. For example, petitioner's parents told Dr. Sandler on August 25, 2009 that petitioner was depressed. Petitioner denied depression when she saw Dr. Sandler on September 1, 2009. Petitioner's parents told Dr. Sandler on August 25, 2009 that petitioner did not want to go back to school because of her classmates' reaction to her illness. On September 1, 2009, petitioner conveyed the impression that she was quite eager to return to school, rejoin her friends, and resume activities. These discrepancies passed without Dr. Sandler's comment.

On September 8, 2009, petitioner and her parents saw Dr. Nichter. Med. recs. Ex. 1, at 34. Using Ativan gave her a paradoxical reaction where she was seeing bugs and it did not assuage her headache. Id. Her headaches occurred at least three times a week and Elavil was not helpful. Excedrin Migraine with caffeine seemed to wire her up as well. Therapy was going well. She could walk more independently and consistently. Her left leg seemed to turn in. She saw Dr. Sandler who did not think petitioner was having a conversion reaction. He was going to try hypnosis on her. Id. On physical examination, she had variable results in her legs. Id. at 35. Sometimes she had giveaway weakness. At other times, the left foot would turn in. There was no ataxia. Dr. Nichter's assessment was that petitioner continued to improve slowly. She had

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[16] Malingering is "the willful, deliberate, and fraudulent feigning or exaggeration of the symptoms of illness or injury, done for the purpose of a consciously desired end." Dorland's at 1099.

[17] Psychosomatic disorder is "a disorder in which the physical symptoms are caused or exacerbated by psychological factors, such as migraine headache, lower back pain, or irritable bowel syndrome. The synonym *psychophysiologic disorders*, used in previous official nomenclatures and defined as 'physical disorders of presumably psychogenic origin,' has been replaced in DSM-IV by the more neutral phrase *psychological factors affecting physical condition*, which may be applied to any physical condition judged to be adversely affected by one or more psychological or behavioral factors, and is subtyped on the basis of the specific factors involved." Dorland's at 552.

[18] See Exhibit AAAAAAA, medical history dated August 1, 2010 prepared by petitioner's father.

some dizziness upon standing which was separate from headache. Dr. Nichter prescribed hypnosis with the psychiatrist. Petitioner's parents were not interested in acupuncture. Id.

Also, on September 8, 2009, petitioner again saw Dr. Sandler. Med. recs. Ex. 7, at 5. Her headaches persisted and were currently 4-5/10 in severity. Dr. Sandler diagnosed petitioner with mood euthymia.[19] He used hypnosis, guided imagery, and Thought Field Therapy. Petitioner had some relief (her headache was then 4/10) with guided imagery. His plan was that petitioner would have no further visits unless needed and she would practice at home. Id.

On September 16, 2009, Dr. Nichter wrote a Transfer Summary for the pediatric Emergency Room. Med. recs. Ex. 1, at 38. The history he wrote was that petitioner developed severe migraine in February 2009 after a sore throat. Id. In light of some mild depression, she saw Dr. Sandler who tried hypnosis with minimal or no success. Id. Petitioner recently went to school and was able to persist until around 1:00 p.m. but not on the subsequent day. Id. She had severe headaches and on the prior night, which were associated with phonophobia and photophobia. Id. There had been a question of numbness and tingling in the left leg. Id. When the headache was less, her leg was nearly normal. Id. She did reasonably well in school. Id. For petitioner's physical examination, petitioner was in a dark room with her parents. Id. Dr. Nichter's assessment was that petitioner had migraines that might be related to Gardasil administered one or two months before the onset of her migraines. Id.

On September 16, 2009, at 1:30 p.m., petitioner went to the Albany Medical Center Emergency Room where she saw Dr. Cha Pranati. Id. at 40. Petitioner's history was gait disturbance and migraine-like headaches. Dr. Pranati writes, "[I]t was thought that these complaints might have been secondary to her Gardasil vaccine, which was given in December 2008. She started with gait disturbance in February 2009. According to mom, she was not able to walk without significant support February 2009 to July 2009." Id. Petitioner's headache was persistent accompanied by photophobia and phonophobia. Id. Medical staff performed multiple investigations, including MRI and MRA, and everything was normal. Id. Her ANA was high at 1:640, but her ds-DNA[20] was normal. Id. Petitioner came to the ER with more severe headache since school opened. While her appetite had decreased, her photophobia and phonophobia were more pronounced. Petitioner's mother said they had tried many different medications for migraine and nothing worked very well for petitioner. Petitioner reported her pain was 9-10/10. Petitioner also complained of an abnormal sensation in her left leg, but she was able to walk without support. Petitioner had a history of two ankle fractures in the past. Id. Petitioner was on Elavil, Periactin, and Endural. Id. at 40-41. On physical examination, she was lying in bed with the lights switched off. Id. at 41. Petitioner had full strength and no sensory deficit. Her aggravated migraine-like headache had persisted for four to five days. All her investigations had been negative. Dr. Dorothy T. Damore, a pediatric neurologist assisting in the Emergency

[19] Euthymia is "a state of mental tranquility and well-being; neither depressed nor manic." Dorland's at 655.

[20] "Ds-DNA" is double-stranded DNA. Dorland's at 568.

Department, recommended doing a lumbar puncture to rule out pseudotumor cerebri. Petitioner received 5 mg of Reglan IV and 1000 mg of Depacon and the lumbar puncture was performed. One hour after receiving Reglan, petitioner reported minimal improvement. Id. Dr. Pranati diagnosed petitioner with headache, likely migraine. Id. at 42. Dr. Pranati did a physical examination which showed petitioner had 5/5 strength in her arms and legs and no sensory deficit. Med. recs. Ex. 553, at 56. Dr. Nichter, in a note to the pediatric emergency department, dated September 16, 2009, commented that the stress of school might have brought out the worst again in petitioner's migraines. Id. at 59.

On September 30, 2009, the physical therapist Adrienne Fil at Sunnyview Rehabilitation Hospital noted that petitioner had had 29 P-T sessions and had shown functional gains, but had a recent setback after a significant increase in her headaches resulting in her going to the emergency room September 16, 2009. Med. recs. Ex. 11, at 10. Petitioner's mother said petitioner had a bad reaction to pain medications with no relief in her pain. Petitioner's lower extremity function, gait quality, and balance declined. Id. Ms. Fil noted that petitioner had low tone with functional mobility with a floppy upper body and left lower extremity despite having strength on muscle testing. Id. at 12. Petitioner had depression in her earlier treatments, frequently reporting she was unable to sleep and had no appetite. Id. As her function improved, she was more social and had better endurance. But with the recent setback, she appeared more depressed. She continued to be unable to attend a full day of school due to headaches and had an aide for safety while negotiating between classes. Id.

On October 6, 2009, Dr. Nichter wrote petitioner's pediatrician, Dr. Kennette, stating he saw petitioner and her parents for petitioner's migraines and gait disturbance. Med. recs. Ex. 1, at 44. The history he recounts is that petitioner developed a sore throat and afterward a profound migraine at the end of February 2009 and went to the emergency room in early March 2009. She had received a Gardasil vaccination a few weeks earlier. Testing included nerve conduction and EMG to rule out Guillain-Barré syndrome. She also had MRI, MRA, and lumbar puncture, the results of which were also unremarkable. Ativan was unsuccessful and she continued to have headaches, which were diffuse, ranging from 4/10 to 8/10. There were no clear precipitators. Elavil was discontinued and she was on Periactin, Propranolol, and Cymbalta. Cymbalta had not affected the severity of the headaches. Dr. Nichter was seeing petitioner now for syncopal episodes occurring at least five to seven times a week during which she would stand up and walk toward the kitchen or another location, have black spots, and be on the floor. She was a bit tachycardic after the event. With the introduction of the Propranolol, these events significantly increased. Her gait was not as efficient after the lumbar puncture as before it, but she was improving. The lumbar puncture was benign and the opening pressure was 16. Dr. Sandler did not see any pathologic or psychological issues. Id. During her physical examination, petitioner wore sunglasses and lay her head on her mother's lap during most of the visit. Id. at 45. Petitioner was able to jump on two feet. She balanced on one foot for about ten seconds. Her gait was slow, but not lurching. Dr. Nichter's assessment was that petitioner's gait continued to improve. Propranolol may have exacerbated her syncope. Id. There was no clear successful intervention in her headaches. Id. at 46. His plan was to decrease the Propranolol and stop at

three- to four- day intervals, continue Cymbalta and Periactin, and to make an appointment with Dr. Argoff to facilitate any new or different pain management such as Botox or acupuncture. Id.

On October 21, 2009, petitioner's mother called Dr. Kennette's office to complain that petitioner had fever, chest pain from coughing, and a migraine-like headache. Med. recs. Ex. 12, at 54. Petiitoner's mother was concerned because petitioner's headaches were getting worse. She wanted to speak with Dr. Kennette. Petitioner's fever the day before was 100.4 degrees. That day it was over 101 degrees. She had a sore throat and cough for over two days, upper chest pain, severe headache with the cough, and "faints" (the notetaker put "faints" in quotation marks) when she tried to stand up. Her heart rate ranged from the 90s to 144 with blood pressure 90s/70s. Dr. Kennette instructed the mother to seek emergency room care. Id.

On October 23, 2009, petitioner and her parents saw Dr. Joel M. Kremer, a rheumatologist. Med. recs. Ex. 10, at 1. They gave a history of a six-week interval between petitioner's second Gardasil and the onset of her symptoms of sore throat and headache. Id. Petitioner's mother has Raynaud's.[21] Id. at 2. Dr. Kremer noted that the etiology of petitioner's severe headaches and various neurologic deficits was obscure at that time. He noted a five-page summary from VAERS (Vaccine Adverse Events Reporting System) comparing events following Gardasil vaccination vs. Menactra vaccination through November 30, 2008. The summary seemed to indicate that there was an increased incidence of general reactions to Gardasil compared to Menactra, specifically pain, paralysis, syncope, vasculitis, and lupus. There were 28 cases of lupus reported following Gardasil compared to six lupus cases reported following Menactra. Dr. Kremer gave this VAERS summary to petitioner's parents. He scheduled further tests: a repeat ANA, CH50, DNA antibody, C3, C4, FSH, LH, cardiolipin antibody, lupus anticoagulant, and cryoglobulins together with a metabolic panel and routine urine. Id.

Also on October 23, 2009, in the evening, petitioner went with her parents to Albany Medical Center Emergency Department, complaining of difficulty breathing at home. Med. recs. Ex. 553, at 52. Over the last three days, she had some increasing congestion, including bringing up a productive sputum. That day, however, she began having a fever and started Tamiflu. However, her cough persisted, similar to a croup cough, and she had stridorous respirations to the point she was having difficulty breathing. Upon arrival in the Emergency Department, her breathing improved significantly and her parents stated that she had significant improvement on the way to the Emergency Department. Id. Dr. John Burton did a physical examination and found some mild tonsillar hypertrophy to the oropharynx, but no exudate or erythema. Id. at 53. Oxygen saturation was normal. She did not have any stridor or retractions. Her lungs were clear without wheezes or rales. Dr. Burton diagnosed petitioner with viral syndrome and tracheitis.

[21] Raynaud's phenomenon is "intermittent bilateral ischemia of the fingers, toes, and sometimes ears and nose, with severe pallor and often paresthesias and pain, usually brought on by cold or emotional stimuli and relieved by heat; it is usually due to an underlying disease or anatomical abnormality. When it is idiopathic or primary it is called *Raynaud disease*." Dorland's at 1430.

He states in the medical record, "In the Emergency Department, the etiology of this patient's difficulty breathing over the last 2 days and particularly this evening was somewhat unclear, although this seems to be consistent with a history of a viral tracheitis." Id. A chest x-ray was normal and she had a normal epiglottis and normal retropharyngeal tissues. Id.

On October 27, 2009, petitioner's hexagonal phospholipid was 7.3 whereas less than 6.2 was negative and greater than 6.2 was positive. Med. recs. Ex. 8, at 5. On the same date, petitioner had an abnormal lupus anticoagulant panel. Id. Petitioner's ANA was 1:1280 with a speckled pattern. Id. at 17.

On November 5, 2009, Dr. Charles E. Argoff, a neurologist with special qualifications in pain management, wrote a progress note. Id. at 47. The history was that petitioner was in her usual state of health until the end of February 2009 when she began to experience a daily headache. "This appeared to be in association with her use of Gardasil. . . ." Id. [Dr. Argoff's record does not reflect that the end of February is nearly three months after December 8th when petitioner received Gardasil.] Testing included lumbar puncture, MRI, MRA, and "electrophysiological studies because she was at times unable to walk." Id. Dr. Argoff writes he spent over 45 minutes in face to face contact with petitioner in the presence of her parents. To date, all diagnostic studies were negative. Petitioner currently complained of daily headaches with photophobia, severe pounding, sharp and stabbing type of headache across her entire head, and inability to function as well as to attend school. In addition, when she took certain medication, she had difficulty walking and had a dystonic reaction to Reglan when the ER at Albany Medical Center gave it to her. More recently, she was prescribed Ambien to help her sleep and she had a similar reaction. Today, petitioner had difficulty walking in Dr. Argoff's office and her parents told him this difficulty occurred frequently. She had been treated with a variety of agents including Cymbalta, Topamax, amitriptyline, Aleve, Periactin, Ativan, Propranolol, magnesium, multivitamins, and vitamin B2 and nothing had helped her. Petitioner complained of words not appearing as words when she looked at them, but she had not seen her ophthalmologist recently. She had not seen a neuro-ophthalmologist either. A pediatric neurologist at Boston Children's Hospital told her that her complaints were somatic, but did not perform any diagnostic studies. Dr. Sandler, a psychiatrist at Albany Medical Center, saw her but did not feel she had any significant psychiatric issues. Id. Petitioner had headaches daily. Id. at 48. On physical examination, petitioner was able to walk normally, but unable to perform tandem heel and toe gait comfortably because she felt unsteady. However, the Romberg sign was negative. Dr. Argoff's impression was that petitioner had chronic neurological symptoms of uncertain etiology. She appeared to have apraxic[22] difficulties from the motor function point of view, but her difficulty with gait was difficult to diagnose. He recommended that petitioner see Dr. Changizi, one of his movement disorder colleagues, for evaluation of any movement disorder. He also recommended that petitioner see Dr. Rheeman, a neuro-ophthalmologist, because of petitioner's difficulty reading words. Petitioner was already scheduled to see Dr.

[22] Motor apraxia is "impairment of skilled movements that is greater than or different in form from that caused by weakness of the affected parts; the patient appears clumsy rather than weak." Dorland's at 121.

David Cornblath at Johns Hopkins University because of his involvement with the Merck Gardasil studies. Dr. Argoff thought petitioner's headaches might be better controlled with the use of botulinum toxin chemosurgical therapy or specific Botox injections. But he deferred this recommendation. Id.

On November 8, 2009, petitioner saw Dr. Charles Rheeman, a neuro-ophthalmologist, to evaluate petitioner for difficulty in reading. Med. recs. Ex. 15, at 2. She gave a history that she developed numerous symptoms in February 2009. Id. She received two doses of Gardasil, the second in December 2008. Id. Since February 2009, she had had daily severe headaches associated with photophobia and phonophobia. Id. She also developed problems with walking and was undergoing physical therapy. Id. Her main visual complaint was difficulty reading because the words "float." Id. She used a paper for alignment in order to read. Id. She also had trouble sleeping and eating, having lost about thirty pounds. Id. She reportedly had a negative MRI and negative lumbar puncture. Id. She had taken numerous migraine headache medicines without relief. Id. Dr. Rheeman stated that petitioner's entire eye examination was normal. Id. He wrote in a letter to Dr. Charles Argoff:

> I do not have a good explanation for why she is having trouble reading. At this point, I could not entirely rule out a non-organic cause. For example, as far as her difficulty ambulating is concerned, you told me you did not find any weakness or numbness on exam. She could barely walk without her mother's assistance today. However, the patient's mom told me [petitioner] was able to walk about two miles trick or treating on Halloween night.

Id.

On November 10, 2009, petitioner and her parents went to Johns Hopkins University to see Dr. David Reid Cornblath, a neurologist, about petitioner's headaches because he consulted with Merck regarding Gardasil. Med. recs. Ex. 3, at 7. Petitioner's father sent in advance a 100-page notebook to Dr. Cornblath on Gardasil adverse reactions. Id. Dr. Cornblath recounted petitioner's short series of headaches in 2007 after a soccer game. The headaches were mild and resolved, and she had a negative head MRI. Petitioner received two Gardasil vaccinations, the first on August 26, 2008, and the second on December 3, 2008. She was well until about February 15, 2009 when she developed a sore throat, fatigue, low-grade fever, and swollen glands, lasting a week. Id. After that, she had headaches, which worsened and were associated with nausea, photophobia, phonophobia, and loss of appetite. Id. Her pediatrician Dr. Kennette diagnosed her on February 26, 2009 with migraine and prescribed Lortab and Imitrex. Id. Symptoms continued and, by March 2009, petitioner developed a profound inability to maintain balance in order to walk, although never having true vertigo or nystagmus. Id. Symptoms continued with severe unremitting headaches for nine months. Id. Over that time, she had extensive testing including MRI and spinal tap, both of which were normal. She saw a number

of physicians, none of whom was able to find her abnormal neurologically. Id. Her grades were excellent (high 80s to 90s except for math where she had a 99), whether home-schooled or back at school. Id.

Petitioner's laboratory studies were normal for the following tests: CBC, cryoglobulins, PT, PTT, hexagonal phospholipids, Russell viper venom, CSF (0 cells, glucose 56, protein 22), CMP, CK, iron, homocysteine, quantitative immunoglobulins, CRP, serum immunofixation, FSH, LH T4, TSH, antithyroglobulin antibodies, thyroid peroxidase antibodies, vitamin D, Lyme C6, EBV, cardiolipin, double-stranded DNA, C3, C4, T-cell subsets, and total complement. Id. Her ANA on October 27, 2009 was 1:1280. On April 6, 2009 and June 30, 2009, her ANA was 1:640. MRA done on June 9, 2009 was normal. MRA of the neck done on October 13, 2009 was normal. MRV done on March 18, 2009 was normal. Brain MRIs done on March 18, 2009 and June 9, 2009 were normal. A nerve conduction study of July 20, 2009 was normal. Id. at 8.

Petitioner filled out a new-patient questionnaire for Dr. Cornblath. Petitioner listed the following symptoms: (1) altered taste and smell; (2) change in appetite; (3) weight loss; (4) difficulty sleeping; (5) fatigue; (6) neck pain; (7) joint pain; (8) difficulty concentrating; (9) dizziness; (10) headaches; (11) lethargy; (12) balance problem; (13) blurred vision; (14) double vision; (15) trouble concentrating; (16) numbness in legs; (17) poor balance; (18) poor coordination; (19) trouble walking; (20) weakness in legs, left more than right; (21) fainting; (22) abdominal pain; (23) hoarseness; (24) shooting pains; (25) fainting spells; and (26) trouble with smell. Id.

Her medications included: Topamax (no effect), Amitriptyline (no effect), Propranolol (no benefit but petitioner developed presyncope); dexamethasone (no effect), Cymbalta (no effect), Ambien (violent hallucinations), and Reglan (created intense anxiety). Id.

On physical examination, Dr. Cornblath found petitioner's gait striking. Id. at 9. When she walked with her mother, petitioner held on quite tightly and appeared as though she were going to fall. Id. But when petitioner walked with Dr. Cornblath, she hardly required any real assistance. Id. She could rise from a chair without the use of her hands. Id. Dr. Cornblath's assessment was that, after a viral infection in mid-February, petitioner developed what became incapacitating daily headaches. Id. Dr. Cornblath stated that he discussed Gardasil with petitioner and her parents:

> I have explained to the family why I do not believe her current symptoms can be related to the Gardasil vaccine. We have gone over the concepts of biological possibility and the kinds of events of a neuroimmune nature that are known to occur following vaccines at a low incidence. Her symptoms began two months after vaccination and were closely in time follow[ing] some sort of viral infection. Thus, I do not believe there is any relationship

> between her current symptoms and her receipt of the Gardasil vaccine.

Id. Dr. Cornblath wrote that the cause of petitioner's headache remained unknown. He pondered whether the dosages of petitioner's various medications had been high enough to work. He suggested that petitioner talk with her physicians about returning to those medications and raising their dosage. Dr. Cornblath spoke with Dr. Nichter who told him that, in treatment of pediatric migraine, low dosage is standard practice. Id.

Dr. Cornblath wrote:

> There is no clear neurological explanation for her gait dysfunction. This has been noted multiple times in her past records where her gait has been called "astasia-abasia."
>
> At the end of the interview, [petitioner] asked me if I thought she was crazy. I told her that she had a serious set of symptoms for which the doctors had been unable to find the cause. However, in most people of her age who have a normal neurologic examination and extensive normal neurological testing, she has an excellent prognosis for her recovery. I explained . . . however that a recovery of her medical condition requires close cooperation with her [doctors] and a positive attitude on her part.

Id. Dr. Cornblath recommended biofeedback as a possible help in a conversation with Dr. Nichter. Dr. Cornblath noted that petitioner's parents were still convinced that Gardasil caused petitioner's problems. Id.

On November 13, 2009, Dr. Kremer, the rheumatologist, spoke with petitioner's mother and then petitioner's father. Med. recs. Ex. 10, at 3. Petitioner had a positive ANA of 1:1280 speckled and a weakly positive hexagonal phospholipid neutralization test with a norm INR, negative anti-cardiolipin antibody, and negative beta 2 glycoprotein 1. Dr. Kremer told both parents that he found it difficult to connect these lab test results with petitioner's clinical picture given the multiple negative imaging studies she had. He recommended they see Dr. Michelle Petrie at Johns Hopkins Medical Center in Baltimore. They mentioned they had just returned from Johns Hopkins after seeing Dr. Cornblath, a neurologist, who suggested increasing petitioner's dosage of Topamax. Dr. Kremer said he would e-mail Dr. Petrie to see if she would consider seeing petitioner as an additional consultant. Id.

On November 17, 2009, petitioner and her parents visited Dr. Nichter. Med. recs. Ex. 1, at 50. Among petitioner's other tests, her sedimentation rate and C-reactive protein were normal. Petitioner and her parents met Dr. Cornblath in Baltimore, and he did not feel that Gardasil was related to her present clinical condition. In a personal phone call Dr. Cornbluth made to Dr.

Nichter, "he stated he thought most of the findings were not physiologic." Id. Petitioner also saw a neuro-ophthalmologist who found her entire eye examination was benign. He raised questions as to stressors in petitioner's life. Petitioner and her parents met with Dr. Sandler who felt she did not have any major psychologic or psychiatric dysfunction, and recommended trazadone for sleep. But after taking Ambien once and having almost a hallucinatory response in terms of seeing death in her brother, petitioner was quite agitated and confused. Petitioner and her parents saw Dr. Argoff who recommended Botox injections but also recommended they see a movement disorder specialist, Dr. Changizi, "but the family did not wish to go that route." Id. Petitioner's headaches waxed and waned. At times, she did well. For example, she walked most likely five miles during a Halloween event. She seemed fatigued, but still walked over three to five miles. After her experience with Ambien, she had a severe headache. Id. Of note, Periactin did not result in significant improvement. Id. at 50-51. Propranolol resulted in a syncopal-like process. Id. at 52. Cymbalta made no difference. On physical examination, petitioner's weakness seemed quite variable. At times, she was weaker on the left than on the right, but it was inconsistent. "She could barely walk during the examination, and yet when coming in, she walked from the parking lot to the sitting room without any assistance." Id. She could not jump on two feet without some assistance. Id. at 51-52. There was some decrease in vibratory sense at the left toe, but it was very inconsistent. Id. at 52. Dr. Nichter's assessment was that petitioner's gait overall was much improved compared to three to four months previously, but there was a dip approximately two months ago. Headache continued to be quite a serious problem. Syncopal events had subsided. Id. Petitioner was not on any medicines and Dr. Nichter did not recommend that she go on any medicines. In light of petitioner's hair falling out, he recommended that she take a good multivitamin with minerals including selenium. He recommended that petitioner and her parents discuss with Dr. Kennette, petitioner's pediatrician, a psychiatric evaluation and specifically any medications that would be a mild mood elevator. Id.

On December 4, 2009, petitioner went to Dr. Michelle A. Petri and Dr. Saru Sachdeva at Johns Hopkins University for a second opinion regarding her headaches and positive ANA. Med. recs. Ex. 5, at 1. Petitioner told Dr. Petri that she had a short series of headaches in 2007 and, on February 15, 2009, she developed a sore throat, low-grade fever, and swollen lymph nodes, lasting for about one week. Id. She also had mild headaches at that time. Id. One week later, on February 21, 2009, her headaches worsened. Id. She was diagnosed with migraine. Id. Her symptoms continued until March. Id. She also developed an inability to maintain balance in order to walk. She did not have vertigo or nystagmus. Id. Her headaches worsened. Id. She began various medications, including multivitamins and melatonin. Id. She had lower extremity weakness and, on June 30, 2009, testing showed she had an elevated ANA. Id. at 1, 2. On November 11, 2009, she saw Dr. Cornblath at Johns Hopkins, who did not feel that Gardasil caused her symptoms. Id. at 2. He evaluated her and did not find any objective evidence of neurological deficits. Id. On October 23, 2009, petitioner had a positive ANA at a titer of 1:1280 and a borderline low hematocrit. Her hexagonal phospholipid was positive. She had a normal Russell viper venom time. Her anti-cardiolipin antibodies were negative. Her iron studies, serum immunoglobulin, and thyroid studies were normal. Her 25-hydroxyvitamin D

was mildly low at 33.6. Petitioner complained of headaches, bluish discoloration of her toes, photophobia, and phonophobia. She was wearing sunglasses. Her mother had possible rheumatoid arthritis although the family is uncertain about this. On review of systems, the pertinent positives were excessive hair loss and bluish discoloration of the toes. She stated she felt dizzy upon getting up from a supine position and felt weakness and numbness in her left lower extremity. She stated her right knee was painful because of over compensation as she used her right leg more. Id.

On physical examination, Dr. Petri did not find any alopecia (hair loss). Id. at 3. Petitioner had livedo[23] around both knees and forearms. There was cyanosis[24] in the toes. On neurological exam, petitioner did not have any objective evidence of sensory or motor deficits. Her Romberg's test was negative. Dr. Petri diagnosed petitioner with undifferentiated connective tissue disease ("UCTD") based on petitioner's positive ANA, Raynaud's disease, livedo, and lupus anticoagulant. Id. She recommended petitioner take Plaquenil. In answer to petitioner's parents' concern that Gardasil caused petitioner's headaches, Dr. Petri wrote that symptom onset was six weeks post-vaccination. (Actually, it was 10 weeks post-vaccination.) Id. Dr. Petri engaged in a detailed discussion with the family. She said there is a mean of three to four years between positive serologies and clinical onset of symptoms in systemic lupus erythematosus ("SLE"). Plaquenil would delay the progression of UCTD to SLE. Ten percent of UCTD progressed to SLE. Petitioner needed to avoid sunlight, garlic, G-CSF, echinacea, melatonin, Bactrim, and alfalfa sprouts. Dr. Petri gave petitioner a headache prevention diet and recommended nortriptyline. Petitioner was advised to take 2.5 mg. of amlodipine for her Raynaud's syndrome. If her lupus anticoagulant remained positive, she should consider starting aspirin. She should stop taking melatonin as this worsened SLE. Dr. Petri recommended petitioner take a tilt table test to rule out neutrally mediated hypotension. Id. Dr. Petri noted that she could not connect petitioner's UCTD to Gardasil. Id.

On December 16, 2009, Dr. Nichter called Dr. Kennette to discuss the apparent lack of effective treatment offered to petitioner as of that date and what, if anything could be considered next. Med. recs. Ex. 12, at 57. Dr. Kennette suggested petitioner's returning to see Dr. Sandler, the psychiatrist, was in her best interests. Id.

On December 17, 2009, Dr. Kennette called Dr. Sandler who said he was ready to see petitioner whenever she was ready to return. Id.

Also on December 17, 2009, petitioner underwent a transthoracic echo, which was abnormal, showing a trace mitral regurgitation, tricuspid regurgitation, and aortic insufficiency.[25] Med. recs. Ex. 13, at 3. She had normal left ventricular function. Id.

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[23] Livedo is "a discolored spot or patch on the skin." Dorland's at 1067.
[24] Cyanosis is "a bluish discoloration." Dorland's at 452.
[25] Mitral regurgitation is "the backflow of blood from the left ventricle into the left atrium, owing to mitral valve insufficiency; it may be acute or chronic, and is usually due to mitral valve prolapse,

On January 6, 2010, petitioner wore a Holter monitor, which showed occasional tachycardia of 160 beats per minute at 1:34 a.m., dizziness reported with normal sinus rhythm and a heart rate of 70 beats per minute, and rare PACs.[26] Id. at 4.

On January 14, 2010, petitioner saw Dr. James O'Brien, a cardiologist, for syncope and palpitations. Id. at 5. He reviewed her January 14, 2010 EKG which showed sinus rhythm with an incomplete right bundle branch block,[27] as well as the results of her January 6, 2010 Holter monitor. Id. Dr. O'Brien attributed petitioner's near syncope to vasovagal[28] intolerance. Id. at 6.

On January 19, 2010, petitioner saw Dr. Nichter. Med. recs. Ex. 18, at 1. The cardiology department at the Children's Hospital at Albany Medical Center felt she met the criteria for POTS. Id.

Also on January 19, 2010, petitioner's hexagonal phospholipid was now 6.2 which was borderline since negative was below 6.2 and positive was above 6.2. Med. recs. Ex. 8, at 5. She again had an abnormal lupus anticoagulant panel. Id. Her ANA was 1:640 with an atypical discrete speckled pattern. Id. at 17.

On February 11, 2010, petitioner saw Dr. O'Brien for an evaluation of her syncope and palpitations. Med. recs. Ex. 13, at 8. An EKG done on February 11, 2010 showed sinus rhythm

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rheumatic heart disease, or a complication of cardiac dilatation." Dorland's at 1621. Tricuspid regurgitation is "the backflow of blood from the right ventricle into the right atrium, owing to tricuspid valve insufficiency." Id. Aortic insufficiency is "defective functioning of the aortic valve, with incomplete closure resulting in aortic regurgitation." Id. at 945.

[26] PAC stands for "premature atrial complex." Dorland's at 1359. Atrial premature complex is "a single ectopic atrial beat arising prematurely, manifest electrocardiographically as an abnormally shaped premature P wave, usually with a slightly increased PR interval. It occurs in normal hearts, sometimes associated with the use of stimulants, but may be associated with structural heart disease." Id. at 395. The P wave is "in the electrocardiogram, the initial deflection of the cardiac cycle, representing excitation of the atria." Id. at 2077. The PR interval is "the portion of the electrocardiogram between the onset of the P wave (atrial depolarization) and the onset of the QRS complex (ventricular depolarization), lasting approximately 0.12 to 0.20 second in the adult. It is the time taken for an impulse to traverse the atrioventricular node, bundle of His, and bundle branches." Id. at 951.

[27] A bundle branch block is an "interruption of conduction in one of the main bundle branches, left or right; the sequence of ventricular depolarization is altered since the impulse reaches one ventricle and then travels to the other." Dorland's at 226.

[28] Vasovagal syncope is a "transient vascular and neurogenic reaction marked by pallor, nausea, sweating, bradycardia, and rapid fall in arterial blood pressure which, when below a critical level, results in loss of consciousness and characteristic electroencephalographic changes. It is most often evoked by emotional stress associated with fear or pain." Dorland's at 1818.

with normal intervals. Id. Dr. O'Brien felt the best diagnosis was vasovagal intolerance. Id. at 9.

On March 1, 2010, Dr. Nichter noted that petitioner's ANA went from 1:1280 to 1:640. Med. recs. at Ex. 18.2, at 1. Her cardiolipin was minimally elevated or basically within normal limits. Id. Her gait had significantly improved and she could almost run. Id. More recently, petitioner developed POTS. Id. She had a vesicular rash on her skin occasionally and a reddish hue on her cheeks, but that did not meet the criteria for a butterfly rash of systemic lupus erythematosus. Id. at 2. Dr. Nichter queried whether there was any relationship between POTS and rheumatological disorders. Id.

On May 20, 2010, Dr. Nichter noted that petitioner had headache with major visual complaints and abnormal autonomic function, although other aspects of autonomic dysfunction, such as sweating, bowel, bladder, and gastric emptying, had been completely normal. Med. recs. Ex. 18.3, at 2-3. Her tests for Hashimoto's encephalopathy and thyroid peroxidases were completely normal. Id. Dr. Nichter stated, "One cannot cogently bring all components to her history into a single story." Id. He said autonomic dysfunction was a consideration. Id.

On July 20, 2010, petitioner saw Dr. Jill M. Abelseth, an endocrinologist. Med. recs. Ex. 17, at 1. Petitioner had normal adrenal and thyroid function studies. Id. at 2.

On July 29, 2010, petitioner had the same borderline 6.2 for hexagonal phospholipid as she had on January 19, 2010. Med. recs. Ex. 8, at 5. Her lupus anticoagulant panel had become borderline whereas, previously, it was abnormal. Id. Testing for AChReceptor[29] ("AChR") (muscle) binding antibody was negative. Id. at 21. Testing for N type calcium channel antibody was negative. Id. Testing for P/Q type calcium channel antibody was negative. Id. at 22. Testing for AChR ganglionic neuronal antibody was negative. Id. Testing for neuronal voltage-gated potassium channel antibody was negative. Id. Petitioner's ANA was 1:1280 with an atypical discrete speckled pattern. Id. at 17.

On August 6, 2010, petitioner saw Dr. Kennette for her 16-year, five-month check-up. Med. recs. Ex. 12, at 60. She had headaches 24/7, which were on a 6/10 scale that day. She had taken a Caribbean cruise in April and was going to Disney World during the New Year. She had low blood pressure attacks and fell down. Her blood pressure was very low and her heart rate dropped usually with body position changes. She was taking Aleve and Tylenol PM. She did minimal walking of less than one mile when tolerated. Her periods were irregular for four

[29] ACh stands for "acetylcholine." Dorland's at 14. Acetylcholine is "a reversible acetic ester of choline; it is a cholinergic agonist and serves as a neurotransmitter at the myoneural junctions of striated muscles, at autonomic effector cells innervated by parasympathetic nerves, at the preganglionic synapses of the sympathetic and parasympathetic nervous systems, and at various sites in the central nervous system." Id. at 12. "Myoneural" pertains "to both muscle and nerve; said of the nerve terminations in muscles." Id. at 1224.

months, ranging from three to eight weeks. She weighed 120 pounds. Her BMI was 19. She seemed sullen and upset. Her heart rate was 68-72. She had a one and one-half year history of daily headaches ranging from 3/10 to "40"/10 (Dr. Kennette used quotation marks), which were unresponsive to myriad interventions. Petitioner's previous episodes of abnormal gait were now resolved. Now she had episodes of syncope secondary to lower blood pressure and abnormal pulse. Her ANA was between 640 and 1280 for the past year. She had Raynaud's disease. Petitioner did not wish to discuss guidance or counseling that day, but desired to keep in regular contact with Dr. Kennette by telephone for "emotional support" (Dr. Kennette used quotation marks). Id. at 60-61. The total time Dr. Kennette spent with petitioner and her parents was one hour and 45 minutes. Id. at 61.

In an addendum to her August 6, 2010 visit notes, Dr. Kennette recorded that petitioner's father brought an extensive set of medical records which included reviews of information that Dr. Kennette had not received, e.g., from Dr. O'Brien, the cardiologist, an update from Dr. Sarah Elmendorf,[30] an infectious disease expert, and information from an upcoming visit to Johns Hopkins Hospital. Id. at 62. Dr. Kennette reviewed the various medication trials, e.g., Florinef (petitioner did not tolerate it), and Midodrine (petitioner did not feel it was helpful). She reviewed laboratory data not previously provided, e.g., EKG, Holter monitor, echocardiogram, and basic metabolic profile, all of which were normal. She reviewed Dr. O'Brien's provisional diagnoses of tachycardia and dysautonomia. Dr. Kennette had an extensive one-on-one interview with petitioner alone to update her on her condition and discuss her current status at home and her impression of how she felt. Plus Dr. Kennette reviewed with petitioner current strategies for school limitations based on her physical abilities. Id. Dr. Kennette discovered after reviewing all of the reports given to her that day by petitioner's family that petitioner had not received the Western blot examination of blood for Lyme disease or empiric treatment for Lyme disease. Id. at 63. Dr. Kennette was going to add a request for the Western blot test to be done on July 29, 2010. After speaking to petitioner's father, Dr. Kennette wanted to empirically treat petitioner for Lyme disease with Doxycycline 200 mg. daily for two to four months and reassess her symptoms. Id.

On August 9, 2010, Dr. Kennette telephoned petitioner's mother. Id. Petitioner had not yet started taking Doxycycline because she was "not feeling well enough to eat much" (Dr. Kennette used quotation marks) over the weekend. Petitioner was going to seek an opinion at Johns Hopkings with Dr. Rowe, a pediatric diagnostic clinician, and might try Doxycycline at a lower dose when she and her parents returned, perhaps 300 mg/day instead of 400 mg/day. Id.

[30] Petitioner did not file any medical records from Dr. Sarah Elmendorf. Petitioner's father testified that he has known Dr. Elmendorf since medical school, they were both on the overgoverning board of the hospital for well over ten years, they have sat on many committees together, and they live six blocks apart. Tr. at 168. He used Dr. Elmendorf as a sounding board to discuss petitioner's condition and treatment, and any avenues petitioner and her parents could pursue for diagnosis and treatment. Id. at 169.

On August 11, 2010, petitioner saw Dr. Peter C. Rowe at Johns Hopkins University for further evaluation of her orthostatic intolerance, fatigue, and other problems. Med. recs. Ex. 6, at 4. She was quite flexible as a child and could put her leg behind her head, had a positive Gorlin sign,[31] and could make a clover-like configuration with her tongue. She had a number of fractures. At age 8, she fell on her wrist and fractured it. She sprained her left ankle soon afterwards, requiring a cast and then a walking boot. At age 11, she fractured her left fourth finger when someone stepped on her hand. At age 12, petitioner had a fracture at the epiphysis of the right ankle while playing soccer and was in a cast and a boot for a total of seven weeks. She underwent nuclear medicine scanning at that time because of persistent pain and concern about complex regional pain syndrome. At age 14, she fractured several bones in the left hand after hyperextending her thumb in volleyball. Also at age 14, she fractured her left fibular in soccer and refractured this bone when she fell walking up stairs. She had some headaches in 2007 that resolved. Id.

Dr. Rowe noted that petitioner did not have an immediate reaction to either of her two Gardasil vaccinations, the first on August 26, 2008 and the second on December 3, 2008. Id. Her main problems began on February 15, 2009, when she suddenly developed a sore throat, fatigue, and swollen glands that lasted a week, followed within five days by a headache, which became progressively worse, associated with photophobia, phonophobia, and diminished appetite. Id. She had not been well since the onset of this illness. By early March 2009, petitioner was collapsing, weak, unable to walk, and spent much of the day reclining. She did not walk much until August 2009. Although Dr. Petrie diagnosed petitioner with UCTD and had recommended Plaquenil, petitioner had not started Plaquenil. Id.

Petitioner had seen cardiologist, Dr. James O'Brien, on December 17, 2009, who felt she had vasovagal syncope and an associated POTS. Id. at 5. Trials of Florinef and midodrine were

[31] The Gorlin sign is "the ability to touch the tip of the nose with the tongue, frequently a sign of Ehlers-Danlos syndrome." Dorland's at 1711. Ehlers-Danlos syndrome is "a group of inherited disorders of the connective tissue; they were formerly classified into ten types, but more recently only six types are distinguished, varying widely in severity. The major manifestations include hyperextensible skin and joints, easy bruisability, friability of tissues with bleeding and poor wound healing, calcified subcutaneous spheroids, and pseudotumors. The *hypermobility type* (formerly type III) is autosomal dominant and most common type; mitral valve prolapse accompanies the skin and joint anomalies. The *classical type* (formerly types I and II) has both autosomal dominant and autosomal recessive subtypes; it includes mitral valve prolapse as well as fibrous growths on pressure areas such as the knees and elbows. The *vascular type* (formerly type IV) is autosomal dominant and is characterized by fragile blood vessels and organs that may rupture, as well as distinctive facial features such as protruding eyes and thin nose and lips. The *kyphoscoliosis type* (formerly type VI) is a rare, autosomal recessive type characterized by kyphoscoliosis and eye fragility accompanying bone and joint anomalies. The *arthrochalasis type* (formerly types VIIA and VIIB) is a rare, autosomal dominant type in which joints are particularly loose and prone to dislocation; patients also suffer from arthritis and bone loss. The *dermatosparaxis type* (formerly type VIIC) is an autosomal recessive type characterized by particularly fragile and sagging skin. Most types are related to defects in procollagen . . . ." Id. at 1828-29.

ineffective. Petitioner increased her intake of salt and fluids. Nevertheless, her systolic pressures have been in the 60-80 range. On electrocardiogram, she had normal left ventricular function, a normal aortic root of 2.5 cm, and echocardiographic evidence of trace mitral regurgitation, tricuspid regurgitation, and aortic insufficiency, but no murmur.

Currently, petitioner reported headaches, lightheadedness, syncope, fatigue, cognitive problems, photophobia, phonophobia, gastrointestinal symptoms, some hair loss, problems regulating temperature, cold feet and hands, numbness in an ulnar distribution which awakened her every other night, insomnia, racing of her heart, occasional shortness of breath, acne, and increased thirst. Petitioner reported a constant headache that never resolved, but also clusters of more intense worsened headaches. Sometimes, the headaches felt like a vise, exerting pressure within her head, and stabbing, causing downward pressure on the top of her head. Loud noises and bright lights aggravated the intensity of her headache, although lately the photophobia had not been as bad. She slept with earplugs. She often skipped breakfast. She stated she never had a problem with lightheadedness and syncope until her illness in February 2009. Her legs would give out in March 2009 and her heart raced. She had a poorly coordinated gait that may have been related to weakness and deconditioning. Lightheadedness and syncope were more clearly reported in April or May 2009 whenever she would move from sitting to standing after she had a month or more of almost total inactivity. Her Holter monitor average heart rate was 76 beats per minute with a range of 52-160 beats. She had a true loss of consciousness with syncope about 12 times over the course of the illness, but syncope was less frequent in recent months. She still had some lightheadedness with dimming of her vision when she stood up, but tended to hold on tightly to something and resolved the lightheadedness fairly promptly. She had a number of orthostatic intolerance postures, such as sitting with her knees to her chest frequently. Fatigue occurred daily, although she had occasional spurts of better energy. Activity and sleeping too much or too little worsened her fatigue. After a syncopal episode, her fatigue was often worse. It was also worse after shopping. Id. Hot weather also worsened her fatigue. Id. at 6. She could force herself to attend a special event or have a special day, but then her malaise increased for one to two days afterward. She had a variable attention span and concentration. Her understanding tended to flag when she was more tired. However, her grades had been good. She was still quite sensitive to sounds within her house although her photophobia and phonophobia were slightly better. Her gastrointestinal symptoms included a sense of tightness in the epigastric area and a feeling that she could not breathe. This occurred less than five days a week and lasted a couple of hours when present. She had reflux one to three times a week and early satiety but no aphthous ulcers. She lost 20 pounds early in her illness, but regained about 10 pounds over the last year. Going off milk for a month did not improve her. She said she had lots of hair in her brushes and in the drains, but she did not have any complete patches of alopecia on examination. Petitioner preferred the temperature in her room to be about 67 degrees and often felt quite hot. Her temperature regulation problems varied substantially. Her parents occasionally found her lying on the hot driveway in the summer sun with winter clothing on, trying to get warm. Her Lyme test, Ehrlichia test, and Babesia test were negative. The family history is notable for allergies in her father and a paternal aunt. Id.

On physical examination, Dr. Rowe detected petitioner had blue sclerae,[32] a positive Gorlin sign, and subluxation/clicking of the temporomandibular joint ("TMJ") with mouth opening. She could place her palms flat on the floor. Since her Beighton score was only 1, she did not meet the full criteria for joint hypermobility. She had diffuse acrocyanosis.[33] He did not see evidence of Raynaud's phenomenon during this visit. Romberg sign was negative. She was a bit unsteady with tandem gait. She had hypermobility on straight leg raise, with stretch elicited at 70 degrees bilaterally, with end-range 120 degrees on the right and 110 degrees on the left, far greater than normal. Dr. Rowe performed a standing test to evaluate petitioner's orthostatic tolerance. Her lowest resting heart rate supine was 47 beats per minute with a blood pressure of 103/56. On standing, she had an immediate increase to 82 beats per minute and continued to increase gradually to a maximum of 98 beats per minute after nine minutes. Id. Petitioner had an initial increase in her lightheadedness with standing that improved after about a minute, but her fatigue level and lightheadedness increased modestly over the 10 minutes of standing. Id. at 7.

Dr. Rowe's assessment was that petitioner had a post-viral fatigue illness that now met the criteria for chronic fatigue syndrome since she had fatigue for more than six months, post-exertional worsening of malaise, new-onset headaches, myalgias, cognitive problems, and unrefreshing sleep. Id. at 7. Petitioner had resting hypotension without formal tilt testing and had recurrent syncope that was consistent with neutrally-mediated hypotension. Her standing test that day was entirely consistent with POTS. She had a 51-beat per minute increase in heart rate within 10 minutes of standing, essentially doubling her heart rate associated with some modest increases in fatigue and lightheadedness. Her heart rate changed despite taking high salt and fluid. Petitioner had a lot in the way of allergies or asthma, some mild acne, and deconditioning. She had a number of phenotypic features usually seen in association with connective tissue laxity, but did not meet the full Beighton score criteria for hypermobility, but had a number of other features, such as blue sclerae, the Gorlin sign, and extreme hypermobility at the hips. Dr. Rowe said, "I suspect the connective tissue phenotype is allowing excessive vascular compliance in the dependent circulation, and is a factor contributing to her orthostatic intolerance, along with the deconditioning, which in turn causes a loss of plasma volume." Id. He suggested petitioner increase her exercise and improve her conditioning status with physical therapy. Id. For the orthostatic intolerance, Dr. Rowe suggested she raise the head of her bed and wear compression garments. She could use postural counter-maneuvers such as clenching

[32] Sclera is "the tough white outer coat of the eyeball." Dorland's at 1678. Blue sclerae is "a prominent feature of osteogenesis imperfecta, and is seen in certain other abnormalities." Id. at 1679. Osteogenesis imperfecta is "a group of inherited connective tissue disorders characterized by brittle, easily fractured bones and sometimes other manifestations, including blue sclerae, wormian bones, shortened limbs and limb deformities, fragile skin, muscle weakness, lax joints, bleeding and easy bruising, hearing loss, dyspnea, and dentinogenesis imperfecta." Id. at 1346.

[33] Acrocyanosis is "symmetrical cyanosis of the extremities, with persistent, uneven blue or red discoloration of the skin of the digits, wrists, and ankles accompanied by profuse sweating and coldness of the digits. Called also *Raynaud sign*." Dorland's at 19.

her fists when she began to stand or when she felt lightheaded. He also suggested petitioner receive two-liter infusions of normal saline over one to two hours to modulate autonomic tone. Id.

On November 2, 2010, petitioner returned to Dr. Rowe much improved after adopting his suggestions, such as raising the head of her bed, increasing her salt intake, and using postural maneuvers. Id. at 9. Her school grades were in the 90s and she was taking up the flute and the drama club. Id.

On January 23, 2011, petitioner saw Dr. Uhl, the orthopedist, with an injured right knee while climbing on a snow bank. Med. recs. Ex. 14, at 28. Dr. Uhl suspected medial collateral ligament injury, but he could not explain her complaint of some numbness. He noted that "in the past the patient has had altered sensations and may be predisposed to RSD [reflex sympathetic dystrophy also known as complex regional pain syndrome[34]]." Id. He also noted that petitioner had a prolonged period of thumb pain "with no specific explanation." Id.

On February 11, 2011, petitioner and her parents saw Dr. Nichter. Med. recs. Ex. 18.4, at 1 . Since her last visit, petitioner had made significant progress. Id. Her gait was basically normal. Id. Her vertigo was much improved. Id. She continued to have headaches. Id. She still had fatigue and some elements of POTS. Id. Fluids and salt had been helpful. Id. She did quite well academically, having an over 90 percent average. Id.

On September 9, 2011, petitioner saw Dr. Kennette, complaining of a sore throat for three days. Med. recs. Ex. 12, at 65. She had a very busy summer and felt good. She was alert, active, and chatty. She was not wearing sunglasses. Dr. Kennette diagnosed petitioner with pharyngitis and tonsillitis. She prescribed penicillin as a "rescue" prescription, but on September 12, 2011, petitioner's throat culture was negative. Id.

On September 12, 2011, petitioner's rheumatoid factor was 22, which is higher than normal, which is below 20. Med. recs. Ex. 8, at 17. Her ANA was 1:640 in an atypical discrete speckled pattern. The normal result should be below 1:320. Id. Her EBV IgG was positive at 1:10 and weakly positive at 1:640. Id. at 16. Her EBV IgM was also positive. Id.

On September 16, 2011, petitioner saw Dr. Kennette for her 17-year, seven-month visit. Med. recs. Ex. 12, at 66. Her monospot test[35] was positive and she had a slight elevation in her white blood cells. Petitioner was in school all day. She had been on penicillin for seven days. She was occasionally on a treadmill. She had normal gait and strength. Petitioner was much improved concerning non-specific chronic headaches, decreased blood pressure with irregular

[34] Dorland's at 585, 1826.

[35] The mononucleosis spot test or monospot test is "a type of heterophile antibody test for infectious mononucleosis. . . ." Dorland's at 1894.

heart rate, and fatigue. She had a recent diagnosis of mono. She had acne, for which Dr. Kennette prescribed Clindamycin.[36]

On September 19, 2011, Dr. Kennette wrote a letter to petitioner's high school, stating petitioner was clearly much improved from the prior year. Id. at 67. However, at times, petitioner might need a modified school environment and/or time frames for assignments and tests. She frequently had headaches, but they were not usually as severe as the ones she had in the past. But she might need access to large print books or books on tape and must be allowed access to frequent water breaks throughout the day. Id.

On October 12, 2012, petitioner saw Dr. David Palat, a pulmonologist, for bronchitis, chest pain, and cough. Med. recs. Ex. 21, at 1. In his review of systems, Dr. Palat notes petitioner had no vision problems. Id. He also notes petitioner did not have palpitations, her heart rate was not fast, and her hands and feet were not cold. Id. at 2. He notes that petitioner did not feel weak. She did not have finger pain or blanching with cold. She did not have arthritis. She did not have localized joint pain or localized joint stiffness. She did not have dizziness, sleep disturbances, or insomnia. Id. Dr. Palat measured petitioner's blood pressure. It was 112/80. Her pulse rate was 84 beats per minute. Id. She weighed 133 pounds and was five feet 7 inches tall. Id. Petitioner's gait and stance were normal. Id. at 3. Dr. Palat's assessment was bronchitis. Id.

On November 21, 2012, petitioner and her mother saw Dr. Jennifer Lindstrom, a pediatrician and internal medicine specialist, for the first time (to replace Dr. Kennette). Med. recs. Ex. 552, at 23. Petitioner's mother believed that Gardasil caused all her medical problems, including gait instability, severe headaches, an elevated ANA, and orthostatic hypotension. Id. Petitioner had been on multiple headache medications without success. Hypnosis failed to help her. Petitioner refused to follow up with neurology again. Petitioner saw a rheumatologist about her elevated ANA and she diagnosed petitioner with undifferentiated connective tissue disease. Petitioner had not followed up on this. Dr. O'Brien recommended petitioner take midodrine and Florinef for her orthostatic hypotension, but petitioner was no longer taking them. She instead tried to follow a high sodium diet. Id. Petitioner was drinking four to eight alcoholic drinks on the weekend, which qualified as binge drinking. Id. at 24. Petitioner's headaches failed to respond to Topamax, Imitrex, Lortab, Cymbalta, Toradol, Compazine, and Benadryl. Id. at 25. Dr. Lindstrom counseled petitioner that four to eight drinks on the weekend qualified as binge drinking. Id. at 24. Petitioner said she would cut back. Id. at 25.

On March 7, 2013, petitioner with her parents saw Dr. Nichter, complaining of a significant exacerbation of her migraines. Med. recs. Ex. 552, at 20. The prior week she had a lot of pain and told her father to cut her head off. The headaches were frontal, temporal, and sometimes extending to the back. They could be 10/10 and petitioner was crying at times. She had photophobia. Id. Petitioner had academic stresses and social stresses with her roommate at

[36] Clindamycin is an antibiotic "effective primarily against gram-positive bacteria." Dorland's at 372.

college. Id. Lortab, Imitrex, Ativan, and Reglan did not improve her headaches, with the latter two causing negative adverse reactions. Benadryl had given her "a buzz" and was not sedative. Id. at 21. Petitioner's physical examination was normal. Petitioner had been in good health. She did not have joint swelling or decline in vision or hearing. Petitioner was "alert and interactive with a wonderful fund of knowledge. She was quite articulate in explaining why she understands playing the role of another person i[s] understanding herself." Id. Dr. Nichter's assessment was that the cause of petitioner's migraines was most likely multifactorial in that stressors had accumulated and exacerbated her migraines. Dr. Nichter discussed with petitioner and her parents going to the emergency room to have a combination of Toradol, Benadryl, and Reglan administered, but they decided not to do that. Id. Dr. Nichter provided the name and telephone number of an acupuncturist. Id.

On March 28, 2013, Dr. Nichter wrote a letter to the campus center of the college petitioner attended, requesting a single dormitory room for her because her living arrangement with a roommate exacerbated petitioner's headaches. Sleeping continued to be a challenging problem for her. Id. at 19.

On January 23, 2014, petitioner saw Dr. Laura El Hage for her annual examination. Id. at 15. Petitioner had chronic daily headache but they did not worsen when she began oral contraceptives. She did not have any abnormal neurologic symptoms such as numbness or weakness during her headaches. Id. Petitioner occasionally used EtOH (ethyl alcohol).[37] Petitioner said she did not binge. She denied any other illicit drug use. She said she woke frequently during the night, 15 times a night and could wake up for an hour at a time. She did not have difficulty walking. All other systems reviewed were negative. Her strength was intact and equal in all four extremities. Sensation was intact throughout. Id. Dr. El Hage diagnosed petitioner with chronic fatigue syndrome and chronic migraine without aura. Id. at 17.

On December 12, 2014, petitioner and her mother again saw Dr. Lindstrom. Id. at 13. Petitioner had general malaise in terms of decreased sleep, daytime fatigue, stressful dreams, inability to focus, and feeling restless. Id. She had some difficulty with her first semester at college and took an incomplete in one course. Petitioner had been crying more. She was interested in going back to see Dr. Nichter whom she had not seen in two years. Id. On physical examination, petitioner was at times almost tearful. Id. Dr. Lindstrom diagnosed petitioner with multiple symptoms of mood disorder, not otherwise specified, with some feelings of reliving stressful dreams, some crying, decreased sleep, and some symptoms of inattention. Dr. Lindstrom believed petitioner needed a neuropsychiatric evaluation to assess her for inattentive disorders, post-traumatic stress disorder, and stress reactions. Dr. Lindstrom thought petitioner

[37] Ethyl alcohol is ethanol. Dorland's at 45. Ethanol is "a primary alcohol existing as a transparent, colorless, volatile, flammable liquid, miscible with water, methanol, ether, chloroform and acetone; it is formed by microbial fermentation of carbohydrates or by synthesis from ethylene. Excessive ingestion results in acute intoxication, with psychological, gastrointestinal, neurological, and motor abnormalities. . . ." Id. at 650.

would benefit from counseling. As for orthostatic hypertension, petitioner's blood pressure was stable that day. Petitioner had been using table salt. She had chronic migraines headaches for which she would see Dr. Nichter. Id. at 14.

On December 31, 2014, petitioner and her parents saw Dr. Nichter. Id. at 9. Stress was an issue for petitioner. Over the last several weeks, she had such difficulty with stress that she would hyperventilate sometimes and have a 15- and 20-minute period where she was not in control of herself. This exacerbated over the last few weeks. She had a significant sleep dysfunction. Before trying to sleep, she would take Tylenol PM, which contains Benadryl, and then perhaps a glass of wine a few times a week. Id. She had daily headaches. She did not take any medication for POTS but used various salts. Id. On physical examination, she had normal gait. Id. at 10. There was nothing to suggest seizures or a neurodegenerative process. She did not have an upper or lower motor neuron disease. Dr. Nichter found her to be "a bright young lady who may have put a number of stressors and possibly too many on her plate." Id. She was "alert, fluent. She had a wonderful fund of knowledge." Id. As for petitioner's sleeping difficulties, Dr. Nichter stated it "would be helpful to decrease and stop the alcohol. It would be helpful to stop the Benadryl and Tylenol PM." Id. Dr. Nichter's plan was for the family to consider counseling vs. psychiatry. The family was fine with the plan. Id.

On March 2, 2015, petitioner saw Dr. El Hage for her annual exam. Id. at 6. Her mother accompanied her. She had chronic daily migraine. Petitioner was using a lot of Aleve (three to six pills per day at 220 mg. each). She did not have any abnormal neurologic symptoms during her headaches. As for her POTS, she had frequent pre-syncopal events, but no true syncopal episodes. She could exercise without difficulty. She denied chest pain or palpitations during exercise. Id. She drank 16 ounces of coffee with two shots of espresso daily. Id. at 7. She lifted weights and used the elliptical machine. Her major was theater and political science. She wanted to do theater professionally. She woke 15 times per night and could wake for an hour at a time. She felt tired in the morning. All other systems were negative. Id. Overall, petitioner was doing well except for her chronic migraines. Id. at 8. Dr. El Hage discussed medication overuse with petitioner and her mother. She recommended that petitioner avoid NSAIDs (Motrin, Advil, Aleve) and take Tylenol as needed for headache. She should avoid Advil because it can cause gastrointestinal side effects and renal issues long term. If petitioner improved, Dr. El Hage would discuss with her that Tylenol can also cause overuse headache and petitioner should be conscientious with its use long term as well. Id.

On March 16, 2015, petitioner saw Dr. Nichter on an urgent basis in light of increased seizure. Id. at 4. Petitioner came with her parents. Approximately two to three weeks earlier, petitioner had increasing headaches. At one point, she came home from college and assumed a fetal position, crying constantly. She tried oxycodone and slept a while. The headache tended to be diffuse and pounding with photophobia and phonophobia. Petitioner switched from Aleve to Tylenol. Yet, on some days, even four days, she took nothing, but on other days, she took five to seven in a day. Probably, every week, she took at least four pills a week. Medications she tried but which failed included Topamax, Benzodiazepine, Reglan, and Maxalt. Two precipitating

factors contributed to her headaches: (1) academic stressors, and (2) sleep dysfunction. Id. Petitioner would pull an all-nighter and then have significant headaches. Yet she had a double major and a minor and was a high achieving student. She did not have any major deficit in terms of gait, vision, or hearing. She did not have swallowing difficulties. She did not have weakness or ataxia. She did not have bowel or bladder problems. She used salts and fluids to help her POTS and they worked reasonably well. Review of systems was benign. Id. On neurological examination, she was normal. Id. at 5. Dr. Nichter wrote: "She is a bright young lady, introspective and has a wonderful fund of knowledge." Id. Dr. Nichter diagnosed her with a history of migraines and a multifactorial stressful life. She had tried acupuncture without success. The drug Restoril did not improve her sleep. Dr. Nichter prescribed Elavil.[38] He advised her to work on her sleep hygiene. Although Dr. Argoff recommended Botox, petitioner said she did not want it. Dr. Nichter also recommended she increase her dosage of melatonin. Id.

On May 7, 2015, petitioner saw PA Sujata Kane, complaining of low back pain and a rash. Id. at 1. Petitioner said she had low back pain for the prior four to five days. She had been lifting a free weight of approximately 50 pounds, which was heavier than what she usually lifted in the gym. She knew her posture was not the best when she did this. She also had a rash on her right lower extremity for two days. Petitioner said she has pre-lupus and a connective tissue disorder with a history of significantly elevated ANA. She told PA Kane she had never been to a rheumatologist. She said she was allergic to Ambien, Reglan, Toradol, Compazine, and Depakote. Id. She said she stopped taking Elavil because she thought it did not work. PA Kane diagnosed petitioner with a back muscle spasm. Id. at 2.

Expert Reports

On June 24, 2013, petitioner filed the expert report of Dr. Yehuda Shoenfeld, an immunologist, as Exhibit 24. He worded his report as answers to seven questions the undersigned raised in the undersigned's Order to Show Cause, dated November 13, 2012.

In answer to question 1, that petitioner had the same symptoms prior to receiving Gardasil as she had after Gardasil, Dr. Shoenfeld responded that she had recovered from these symptoms in 2007 and they did not cause long-term disability. Ex. 24, at 1.[39] Moreover, she had new symptoms after Gardasil, including recurrent syncope, fatigue, neck pain, joint pains, numb legs, cognitive disturbances, blurred vision, unrefreshing sleep, tachycardia, dyspnea, impaired thermoregulation, cold extremities (subsequently diagnosed as Raynaud's disease), toe discoloration, excessive hair loss, gastrointestinal disturbances, lessened appetite, altered sense of taste, and significant weight loss. Id. She also had positive findings for ANA, anti-phospholipid antibodies, and lupus anticoagulant. Id. Dr. Shoenfeld stated none of these

[38] Elavil is an antidepressant also used for chronic pain. Dorland's at 598, 63

[39] Dr. Shoenfeld's expert report is not paginated. The undersigned is using the page numbers on the top right of the page that are part of the CM-ECF system.

manifestations was present prior to her February 2009 illness. Id. To Dr. Shoenfeld, that meant Gardasil triggered them. Id. He did not mention, much less discuss, petitioner's prior viral illness on February 15, 2009.

In answer to question 2, that the 2007 symptoms dissipated and then returned after the February 15, 2009 viral illness, Dr. Shoenfeld responded that petitioner's 2009 viral illness was only presumed because she had flu-like symptoms such as sore throat and enlarged nodes, but not actually verified by laboratory testing. Id. Tests for bacterial infection were negative. Id. Dr. Shoenfeld doubted that petitioner's flu-like symptoms in 2009 were viral-based because they are well-recognized symptoms for chronic fatigue syndrome ("CFS"), otherwise known as myalgic encephalomyelitis. Id. Dr. Shoenfeld believed petitioner satisfied the criteria for CFS because she had persistent fatigue for over six months, headaches, unrefreshing sleep, and cognitive disturbances. Id. He then related that flu-like symptoms and CFS are associated with certain vaccines, particularly vaccines containing aluminum and other adjuvants. Id. He stated that because vaccines induce an immune response similar to infections, they may also trigger autoimmune and immune-mediated inflammatory diseases, just as infections do. Id. Unlike infections, however, vaccines frequently contain adjuvants, and Dr. Shoenfeld stated these adjuvants enhance immune stimulation above the levels of natural infections. Id. To Dr. Shoenfeld, this enhancement suggested "vaccines may provoke more exaggerated, anarchic immune responses than infections." Id. at 2. He found his observation particularly relevant because vaccines, including Gardasil, typically are administered repeatedly over relatively short periods of time, i.e., weeks or months. Id. Dr. Shoenfeld continued that vaccines have been reported to precede CFS after exposure to multiple vaccinations and/or as an adverse response to a vaccine adjuvant. Id. He stated that, since petitioner's symptoms began after her second Gardasil, "it is probable that her illness was triggered by an exaggerated pathological vaccine-related autoimmune response." Id. Dr. Shoenfeld mentioned numerous VAERS reports of similar adverse manifestations, i.e., headaches, myalgia, fatigue, weakness, dizziness, flu-like symptoms, autoimmune disorders, with comparable symptom onset, i.e., two to four months, following receipt of Gardasil booster shots. Id.

In answer to question 3, that all of petitioner's treating doctors noted the significance of petitioner's February 15, 2009 viral illness, Dr. Shoenfeld responded that these doctors only presumed a virus was the cause based on her symptom presentation and not on any concrete laboratory findings. Id. But, because flu-like symptoms are recognized as within the CFS diagnosis, and CFS is "solidly linked" to vaccines, especially those containing aluminum adjuvant, including Gardasil, he believed petitioner's flu-like symptoms were due to her CFS and not to a viral illness. Id. Dr. Shoenfeld also noted that VAERS reports describe flu-like illnesses and thus are "possible adverse reactions to vaccines." Id.

In answer to question 4, that there was a two-month interval between petitioner's second Gardasil and the onset of her renewed symptoms, Dr. Shoenfeld responded that a two-month onset is not unusual for vaccine-related cases and has been previously reported after Gardasil. Id. He noted that this is shown in supplementary Table 1, but did not provide this table with his

report. Id. Dr. Shoenfeld then cited to a medical case report of a teenage girl who died unexpectedly six months after her third Gardasil booster. Id. In the autopsy blood and splenic tissues HPV-16 L1 gene DNA fragments corresponding to 16 separate Gardasil vials from different vaccine lots, suspected of being contaminants, were found, suggesting Gardasil caused her death. Id. at 2-3. These particles were protected from degradation because they were bound to particulate aluminum adjuvant used in the vaccine formulation. Id. at 3. In another case report, Dr. Shoenfeld said there were three cases of systemic lupus erythematosus, including exacerbation of pre-existing lupus, after Gardasil vaccination. Id. Symptom onset was between two to four months post-vaccination. Id. Dr. Shoenfeld's search of VAERS reports of those complaining of flu-like symptoms, chronic fatigue, myalgia, headaches, weakness, dizziness, joint pains, weight loss, photophobia, and lupus occurred mostly two to four months after Gardasil. Id. He attributed flu-like symptoms and chronic fatigue to autoimmune illness following Gardasil acting as the trigger. Id. Dr. Shoenfeld thought that treating doctors do not attribute these events to the vaccine and frequently misdiagnose them as due to viral or microbial illness despite lack of corroborative serological evidence. Id.

In answer to question 5, asking how Gardasil significantly aggravated petitioner's pre-existing symptoms, Dr. Shoenfeld responded that individual susceptibility factors play an important role in determining the severity of adverse reactions. Id. Those risk factors include a previous history of relevant symptoms and a family history of Raynaud's disease. Id. These may have made petitioner more susceptible to having a serious adverse reaction after Gardasil. Id. Referencing a case study, Dr. Shoenfeld said that two out of three lupus cases fitting the criteria for ASIA following Gardasil were exacerbations of pre-existing conditions. Id. He noted that 21 percent of hepatitis B vaccine ASIA cases had either a personal or family history of autoimmune diseases, referencing another article. Id. Since the estimated occurrence of autoimmunity in the general population is from 5-8 percent, Dr. Shoenfeld suggested that those with susceptibility are more likely to suffer disease exacerbation after vaccination. Id.

In answer to question 6, asking how the February 15, 2009 viral syndrome is not itself the trigger of petitioner's post-viral fatigue syndrome, Dr. Shoenfeld responded that his answers to questions 2-4 respond to that. Id. at 4. He also stated that based on petitioner's clinical presentation, her flu-like symptoms were most likely an adverse reaction to Gardasil. Id.

In answer to question 7, asking why the advice of one of petitioner's treating doctors, Dr. Rowe, to increase her salt, exercise, and raise her pillow, was effective and caused her to improve, Dr. Shoenfeld responded that those suggestions are standard for the management of POTS and not surprisingly recommended to petitioner. Id. All POTS patients require a high salt diet, copious fluids, and specific postural exercise training. Id. The high salt and fluid intake increase the patient's blood pressure and decrease her orthostatic dizziness. Id. Sleeping in a position that tilts the head up decreases orthostatic hypotension. Id. Exercise improves symptoms markedly in POTS patients, especially those with chronic fatigue. Id.

On July 19, 2013, respondent filed the expert report of Dr. J. Lindsay Whitton, an immunologist, discussing Dr. Shoenfeld's ASIA hypothesis, and disputing its scientific credibility. Ex. A.

On July 19, 2013, respondent filed the expert report of Dr. Edward W. Cetaruk, a toxicologist, discussing Dr. Shoenfeld's ASIA syndrome, and disputing its reliability. Ex. W.

On December 6, 2013, respondent filed three expert reports: (1) Dr. Carlos Rosé, a pediatric rheumatologist; (2) Dr. Max Wiznitzer, a pediatric neurologist; and (3) Dr. Stephen McGeady, a pediatrician and immunologist. Dr. Rosé, the pediatric rheumatologist, states that petitioner has undifferentiated connective tissue disease ("UCTD"). He states that UCTD is "a very useful concept to typify individuals who present with clinical and serologic features suggestive of a connective tissue disease (CTD) but who do not meet criteria for a definable CTD like Systemic Lupus, Sjögren's or scleroderma but yet may be at risk for developing a significant disease over time. Dr. [Michelle] Petri made the diagnosis based on Raynaud's symptoms, positive ANA and elevated values for Lupus anticoagulant (hexagonal phospholipid test). None of [petitioner's] ongoing additional symptoms (migraine headaches, dizziness, gait abnormality) was part of her rationale for the clinical diagnosis." Ex. RRR, at 6.

Dr. Rosé notes that petitioner's gait abnormality had no physical basis. He notes that three of petitioner's treating neurologists diagnosed her with astasia-abasia, i.e., a non-physiologic phenomenon, "a bizarre gait that does not correspond to any specific area of neurologic deficit." Id. at 8. Dr. Rosé also notes that almost two years before her Gardasil vaccinations, petitioner had migraine and, in 2008 (also pre-vaccination), a mild form of regional pain syndrome. Id. Dr. Rosé was "of the opinion that her progression to intractable migraine complicated by astasia-abasia is nothing more than the natural course of chronic pain, a concept known as pain amplification syndrome." Id. He also states that the association of conversion disorder and migraine is "not new or rare." Id. Dr. Rosé has treated children with chronic pain, frequently combined with fatigue, migraine, and POTS, and in his 30 years of experience, he has not found immune or inflammatory mechanisms to be important in those conditions. Id. at 11. As for Dr. Shoenfeld's ASIA syndrome, Dr. Rosé doubts it exists. Id. at 12.

Dr. Wiznitzer, the pediatric neurologist, notes that petitioner had a history of headache with light and noise intolerance and dizziness in 2007 (pre-vaccination) that persisted and then resolved. Ex. BBBB, at 9. In February 2009, petitioner had an acute illness with fever, sore throat, and swollen lymph nodes associated with headache. Id. Her headache quickly evolved into a chronic daily headache pattern, which stress provoked or exacerbated. Id. Petitioner had documented give-away weakness and gait disturbance diagnosed as astasia-abasia, which was not physiologic but a well-known feature of conversion disorder. Id. Dr. Wiznitzer questioned the diagnosis of petitioner with POTS because there were key clinical features of POTS absent at the beginning. Id. Petitioner showed changes affecting heart rate, and occasionally blood pressure, later. Id. Dr. Wiznitzer explains these symptoms by citing the conclusions of Dr. Peter Rowe of Johns Hopkins Hospital, who, on August 11, 2010, "suspected that [petitioner's]

connective tissue phenotype was allowing excessive vascular compliance in the dependent circulation and was a factor contributing to her orthostatic intolerance along with deconditioning which in turn caused a loss of plasma volume." Id. Dr. Wiznitzer notes that petitioner's connective tissue phenotype predates her receipt of Gardasil vaccines in 2008. Id. He also notes that POTS frequently appears after an identifiable trigger, such as a viral illness or a period of prolonged disability, which occurs in individuals with chronic daily headache. Id. To Dr. Wiznitzer, that identifiable trigger, if petitioner's POTS started in February 2009, was her acute illness, or if it started months later, her chronic daily headache. Id. Dr. Wiznitzer also notes that petitioner's episodes of syncope were associated with her taking Propanolol and they significantly improved when she stopped taking it. Id. Dr. Wiznitzer concludes that petitioner's acute viral illness in February 2009 and the psychological problems associated with her conversion disorder are sufficient to explain her symptoms. Id. at 10. He states there is no evidence or biologically plausible model to associate petitioner's December 2008 Gardasil vaccinations with her 2009 clinical complaints. Id.

Dr. McGeady, the pediatrician and immunologist, states that ASIA is an unproven hypothesis. Ex. MMMM, at 4. He opines that there is scant evidence of autoimmunity in petitioner's illness. Id. at 5. He notes that Dr. Shoenfeld acknowledges that autoantibodies are often present for more than a year before any clinical manifestation of disease. Id. None of the petitioner's tests for acute inflammation was abnormal: white blood cell numbers, platelet counts, erythrocyte sedimentation rates (ESR), C-reactive protein determinations, and complement component determination. Id. Dr. McGeady does not agree that petitioner's elevated ANA and hexagonal phospholipids reflected she had an ongoing autoimmune process. Id. at 6. Although Dr. Shoenfeld described petitioner as having an anamnestic response[40] to Gardasil vaccine, Dr. McGeady notes that petitioner did not have an abnormal response to her first vaccination and, after her second vaccination, two months elapsed until the onset of her symptoms, thus belying an anamnestic response. Id. He notes that petitioner's symptoms did closely follow a sore throat, low-grade fever, and possible sinusitis. Id. Dr. McGeady also notes that the medical records do not contain evidence of an acute inflammatory process following either petitioner's first or second Gardasil vaccination. Id. at 6-7. Dr. McGeady comments that in Dr. Shoenfeld's paper The Mosaic of Autoimmunity: Hormonal and Environmental Factors in Autoimmune Disease (2008) which is Ex. 134, Dr. Shoenfeld identifies stress as a trigger for autoimmune disease. Ex. MMM, at 7. Dr. McGeady notes that when petitioner became symptomatic, her grandmother had died and her father had surgery. Id. He comments that Dr. Shoenfeld does not consider stress as a trigger in his opinion, but blames Gardasil instead. Id.

[40] An anamnestic response is also called a "secondary immune response," which occurs "on the second and subsequent exposures to an antigen; compared to a primary immune response, the lag period is shorter, the peak antibody titer is higher and lasts longer, IgG production predominates, the antibodies produced have a higher affinity for the antigen, and a much smaller dose of the antigen is required to initiate the response." Dorland's at 1629.

Dr. McGeady was not impressed with the literature petitioner submitted in defense of the ASIA syndrome, most of which literature Dr. Shoenfeld wrote. Id. at 8. He states ASIA is not a generally accepted diagnosis. Id. Dr. McGeady concludes that petitioner was susceptible to developing an autoimmune disease but, so far, had not done so. Id. at 10. Her susceptibility is based on a family history of maternal Raynaud syndrome and petitioner's having an autoantibody. Id. Dr. McGeady states that whatever condition "beset" petitioner in February 2009 "has defied diagnosis." Id. POTS alone would not have caused all her symptoms. Id. Three of her treating doctors opined that her condition had a non-organic cause. Id.

Dr. McGeady attached to his expert report an article entitled Postural tachycardia syndrome following human papillomavirus vaccination, by S. Blitshteyn, Eur J Neurol doi:10.1111/ene.12272: 1-5 (Epub Sept. 16, 2013) (see also, 21 Eur J Neurol 1:135-39 (2014) (references will be to the page numbers of the electronic version filed as exhibit OOOO).[41] In this article, Dr. Blitshteyn describes six patients who developed POTS six days to two months after receiving Gardasil. Ex. OOOO, at 1, 2, and 4. Dr. Blitshteyn states that POTS is a heterogeneous disorder, which may arise from various mechanisms and etiologies, but recently there is evidence that POTS may be an autoimmune disorder. Id. at 4. Based on the finding of several types of antibodies in patients with POTS, Dr. Blitshteyn writes she considers POTS "an attenuated form of autoimmune autonomic neuropathy in a subset of patients." Id. The antibodies she describes are to ganglionic N-type acetylcholine receptors, various cardiac proteins, and ß1/2 adrenergic and M2/3 muscarine receptors. Id. Based on these findings of several autoantibodies in a subset of patients, Dr. Blitshteyn writes that POTS is considered to be an autoimmune autonomic neuropathy in that subset of patients. Id. She writes that a virus, surgery, pregnancy, or trauma are common triggers of POTS in a subset of patients. Id. She writes possible pathogenesis of the subset of POTS that is autoimmune after Gardasil may include molecular mimicry in which human papillomavirus vaccine epitopes may induce formation of cross-reacting antibodies against potential targets of the autonomic ganglia, neurons, cardiac proteins or ß1/2 adrenergic and M2/3 muscarine receptors. Id. She also states that bystander lymphocyte activation and a broad spectrum of cytokine responses that human papillomavirus vaccine elicits may also be involved. Id. Dr. Blitshteyn relates the onset of POTS in the six subjects of six days to two months post-Gardasil to the onset timeframes of GBS and acute disseminated encephalomyelitis ("ADEM") after vaccination, and says they are consistent with these well-known post-vaccination syndromes. Id.

(Of interest in the instant action is the fact that doctors tested petitioner for reactivity to ganglionic neurons, and the result of the testing was negative, indicating petitioner's POTS was not autoimmune in nature and she was not in the subset of patients who had autoimmune POTS.

[41] Petitioner also filed this article as Exhibit 426. Petitioner also filed a Letter to the Editor by Dr. Blitshteyn entitled Postural tachycardia syndrome after vaccination with Gardasil, 17 Eur J Neurol 7:e52 (2010); doi:10.1111/j.1468-1331.2010.0321.x. Ex. 425. Dr. Blitshteyn writes that an autoimmune etiology for POTS has been implicated in about 14 percent of patients with POTS after detection of ganglionic acetylcholine receptor antibody. Id. at 1.

Med. recs. at Ex. 8, at 22. Therefore, petitioner's POTS does not fit within the subset of POTS Dr. Blitshteyn described in her article as being an autoimmune autonomic neuropathy.)

Dr. Blitshteyn also mentions that two of the patients experienced significant symptomatic exacerbation following a re-challenge with a subsequent Gardasil vaccination, a phenomenon suggesting a more robust autoimmune response yielding more severe symptoms with subsequent receipt of Gardasil vaccine. Id. (Of interest in the instant action is the fact that petitioner had no adverse reaction to her first Gardasil vaccination, unlike the two patients Dr. Blitshteyn describes.)

None of the six patients in Dr. Blitshteyn's study had a family history of autoimmune disorders. Id. (In the instant action, petitioner has a family history of Raynaud's syndrome and a pre-vaccination onset of antinuclear antibodies.) Dr. Blitshteyn concludes her article with the statement that Gardasil is possibly associated with POTS, but further studies are necessary to determine if there is a causal relationship. Id. at 5.

On March 13, 2014, Dr. Shoenfeld responded to respondent's Dr. Rosé's expert report. Ex. 472. He dismisses Dr. Rosé's focus on petitioner's pre-vaccination history of headaches, dizziness, photophobia, and phonophobia in 2007 because these symptoms resolved. Id. at 2. Dr. Shoenfeld states that "the vaccine **could have been a possible** triggering factor, or at the very least, the exacerbating factor [emphasis added]." Id. at 3. He adds, "[A[n immune-based etiology of POTS would support the idea that the vaccine **may have been** involved . . . . [emphasis added]" Id. Dr. Shoenfeld admits that not all cases of POTS are autoimmune, and states a fraction of POTS cases are autoimmune. Id. at 4. Dr. Shoenfeld cites a paper by Dr. Phillip A. Low and colleagues on POTS, in which they found that ganglionic acetylcholine receptor antibody was detected in 14.6 percent of the POTS cases. Id. Besides antibody to ganglionic acetylcholine receptors in POTS patients, Dr. Shoenfeld states other researchers have identified other autoantibodies, including antibodies to various cardiac proteins, to β1/2-adrenergic and M2/3 muscarinic receptors, and to calcium channels. Id. at 4-5. He concludes that some orthostatic syndromes are autoimmune. Id. at 5. In addition, he confirms that orthostatic hypotension syndromes including POTS are a form of autoimmune autonomic neuropathy in a subset of patients. Id. at 5-6. He estimates that 40 percent of patients with chronic fatigue syndrome ("CFS") also have POTS. Id. at 6.

In discussing petitioner's case, Dr. Shoenfeld summarizes the letter to the editor and article of Dr. Blitshteyn (discussed in Dr. McGeady's expert report). Id. at 7-8. Dr. Shoenfeld finds it "rather unfortunate" that three of petitioner's neurologists labeled her symptoms as psychogenic. Id. at 8.

Dr. Shoenfeld also opines that autoimmune neuropathies associated with Gardasil vaccination can occur up to four to ten months post-vaccination. Id. at 14.

On September 16, 2014, respondent filed Dr. Cetaruk's response to Dr. Shoenfeld's July 3, 2013 report regarding ASIA. Ex. PPPP. Dr. Cetaruk calls Dr. Shoenfeld's ASIA theory untested and unestablished. Id. at 3.

On June 22, 2015, respondent filed the supplemental expert report from Dr. Whitton, again criticizing Dr. Shoenfeld's ASIA hypothesis. Ex. BBBBBB.

Treating Doctors who Opined Petitioner had no physical abnormality or Gardasil was unrelated to her symptoms

On May 4, 2009, petitioner and her parents saw Dr. Magdi Sobeih, a behavioral neurologist, at Children's Hospital in Boston. Med. recs. Ex. 2, at 1. Dr. Sobeih saw petitioner to evaluate her headache and walking difficulties. "After a thorough evaluation I have concluded that there are no neurobiological abnormalities or neuropathological concerns to [L.A.M.]'s complaints." Id. He stated, "I do not feel there is any association between the Gardasil HPV vaccine and the onset of these symptoms." Id. He continued:

> I discussed this at length with the parents. I discussed that this is presenting as a mood disorder that needs appropriate care. . . . It would be very important to[o] that [petitioner] continue under the care of appropriate psychological or psychiatric services and someone to monitor her response to any medications such as amitriptyline. However I do not feel there is any need for any further neurological workup or followup. I discussed this with the parents and with [petitioner] and I counseled further mental health care should be provided.

Id. at 3-4.

On May 14, 2009, petitioner and her parents saw Dr. Nichter, a neurologist. Med. recs. Ex. 553, at 108. Since her last visit, petitioner saw a pediatric neurologist in Boston who felt she had a major psychological or psychiatric component to her ill-defined headache syndrome, and was not convinced that petitioner had migraines. Id. Petitioner's mother stated that petitioner's headaches were better but quite variable. Id. What was most pronounced was petitioner's abasia-atasia type gait. Id. Petitioner was unable to walk. There was no new weakness. Id. On physical examination, she had giveaway weakness but, when this problem was mentioned to her, she had 5/5 strength. Id. at 109. She would bear weight, but had lurching, swaying movements when trying to walk. She would say "sharp" when a dull object was placed on her leg, but her responses were inconsistent. Id. Dr. Nichter prescribed a mood elevator (Elavil). Id.

On November 8, 2009, petitioner and her parents saw Dr. Charles Rheeman, a neuro-ophthalmologist, to evaluate petitioner for difficulty in reading. Med. recs. Ex. 15, at 2. He wrote in a letter to Dr. Charles Argoff, a neurologist specializing in pain management:

> I do not have a good explanation for why she is having trouble reading. At this point, I could not entirely rule out a non-organic cause. For example, as far as her difficulty ambulating is concerned, you told me you did not find any weakness or numbness on exam. She could barely walk without her mother's assistance today. However, the patient's mom told me [petitioner] was able to walk about two miles trick or treating on Halloween night.

Id.

On November 10, 2009, petitioner and her parents went to Johns Hopkins University to see Dr. David Reid Cornblath, a neurologist, about petitioner's headaches because he consulted with Merck regarding Gardasil. Med. recs. Ex. 3, at 7. On physical examination, Dr. Cornblath found petitioner's gait striking. Id. at 9. When she walked with her mother, petitioner held on quite tightly and appeared as though she were going to fall. Id. But, when petitioner walked with Dr. Cornblath, she hardly required any real assistance. Id. She could rise from a chair without the use of her hands. Id. Dr. Cornblath's assessment was that, after a viral infection in mid-February, petitioner developed what became incapacitating daily headaches. Id. Dr. Cornblath stated that he discussed Gardasil with petitioner and her parents:

> I have explained to the family why I do not believe her current symptoms can be related to the Gardasil vaccine. We have gone over the concepts of biological possibility and the kinds of events of a neuroimmune nature that are known to occur following vaccines at a low incidence. Her symptoms began two months after vaccination and were closely in time follow[ing] some sort of viral infection. Thus, I do not believe there is any relationship between her current symptoms and her receipt of the Gardasil vaccine.

Id. Dr. Cornblath also wrote:

> There is no clear neurological explanation for her gait dysfunction. This has been noted multiple times in her past records where her gait has been called "astasia-abasia."
>
> At the end of the interview, [petitioner's mother] asked me if I thought she was crazy. I told her that she had a serious set of symptoms for which the doctors had been unable to find the cause. However, in most people of her age who have a normal neurologic examination and extensive normal neurological testing, she has an

> excellent prognosis for her recovery. I explained . . . however that a recovery of her medical condition requires close cooperation with her [doctors] and a positive attitude on her part.

Id.

On November 17, 2009, petitioner and her parents saw Dr. Nichter again. Med. recs. Ex. 553, at 87. He wrote that petitioner had a profound migraine at the end of February, two months after her Gardasil vaccination. Id. Nerve conduction, EMG, MRI, MRA and lumbar puncture results were unremarkable. Id. at 87-88. In a personal phone call Dr. Nichter had with Dr. Cornblath, a neurologist in Baltimore, after petitioner and her parents had seen Dr. Cornblath, Dr. Cornblath told Dr. Nichter that he thought most of petitioner's findings were not physiologic (i.e., had no physical basis). Id. at 88. Petitioner had also seen a neuro-ophthalmologist who looked at her retina and found her entire eye examination benign. Id. This doctor asked about the stressors in petitioner's life. Id. Petitioner's headaches waxed and waned. Id. Petitioner walked for probably five miles during a Halloween event the prior evening. Id. On physical examination, petitioner was quite variable as for weakness. Id. at 89. At times, she was weaker on the left than on the right, but it was inconsistent. Id. She could barely walk during the examination, but when petitioner was coming in, she walked from the parking lot to Dr. Nichter's waiting room without any assistance. Id. Dr. Nichter's plan was to discuss with Dr. Karen Kennette, petitioner's pediatrician, a psychiatric evaluation for petitioner and whether petitioner should be on a mild mood elevator. Id. at 90.

On December 4, 2009, petitioner and her parents went to Dr. Michelle A. Petri and Dr. Saru Sachdeva, rheumatologists, at Johns Hopkins University for a second opinion regarding her headaches and positive ANA. Med. recs. Ex. 5, at 1. Her mother had possible rheumatoid arthritis, although the family was not certain about it. Id. at 2. On neurological exam, petitioner did not have any objective evidence of sensory or motor deficits. Id. at 3. Her Romberg's test was negative. Dr. Petri diagnosed petitioner with undifferentiated connective tissue disease ("UCTD") based on petitioner's positive ANA, Raynaud's disease, livedo, and lupus anticoagulant. Id. She recommended petitioner take Plaquenil. In answer to petitioner's parents' concern that Gardasil caused petitioner's headaches, Dr. Petri wrote that symptom onset was six weeks post-vaccination. (Actually, it was 10 weeks post-vaccination.) Id. Dr. Petri engaged in a detailed discussion with the family. She said there is a mean of three to four years between positive serologies and clinical onset of symptoms in systemic lupus erythematosus ("SLE"). Plaquenil would delay the progression of UCTD to SLE. Ten percent of UCTD progresses to SLE. Id. Dr. Petri noted that she could not connect petitioner's UCTD to Gardasil. Id.

On May 20, 2010, petitioner and her parents saw Dr. Nichter, who noted that petitioner had headache with major visual complaints and abnormal autonomic function, although other aspects of autonomic dysfunction, such as sweating, bowel, bladder, and gastric emptying, had

been totally normal. Med. recs. Ex. 18.3, at 2-3. Dr. Nichter stated, "One cannot cogently bring all components to her history into a single story." Id.

On August 11, 2010, petitioner saw Dr. Peter C. Rowe at Johns Hopkins University for further evaluation of her orthostatic intolerance, fatigue, and other problems. Med. recs. Ex. 6, at 4. Dr. Rowe assessed petitioner as having "a post viral fatigue illness that now meets criteria for chronic fatigue syndrome given her fatigue for more than 6 months, post exertional worsening of the malaise, new-onset headaches, myalgias, cognitive problems, and unrefreshing sleep." Id. at 7. He said, "I suspect the connective tissue phenotype is allowing excessive vascular compliance in the dependent circulation, and is a factor contributing to her orthostatic intolerance, along with the deconditioning, which in turn causes a loss of plasma volume." Id. Petitioner was still deconditioned. He suggested petitioner increase her exercise and improve her conditioning status with physical therapy. Id. For the orthostatic intolerance, Dr. Rowe suggested she raise the head of her bed and wear compression garments. She could use postural counter-maneuvers such as clenching her fists when she began to stand or when she felt lightheaded. He also suggested petitioner receive two-liter infusions of normal saline over one to two hours to modulate autonomic tone. Id.

On November 21, 2012, petitioner and her mother saw Dr. Jennifer Lindstrom, a pediatrician and internal medicine specialist. Med. recs. Ex. 552, at 23. Petitioner's mother believed that Gardasil caused all her medical problems, including gait instability, severe headaches, an elevated ANA, and orthostatic hypotension. Id. Petitioner had been on multiple headache medications without success. Hypnosis failed to help her and she refused to follow up with neurology again. Petitioner saw a rheumatologist about her elevated ANA and was diagnosed with undifferentiated connective tissue disease. She had not followed up on this. Dr. O'Brien, recommended petitioner take midodrine and Florinef for her orthostatic hypotension, but she was no longer taking them. She instead tried to follow a high sodium diet. Id. Petitioner was drinking four to eight alcoholic drinks on the weekend, which qualified as binge drinking. Id. at 24.

On December 12, 2014, petitioner and her mother again saw Dr. Lindstrom. Id. at 13. Petitioner had general malaise in terms of decreased sleep, daytime fatigue, stressful dreams, inability to focus, and feeling restless. Id. Dr. Lindstrom recommended petitioner get a neuropsychiatric evaluation and counseling. Id. at 14.

On December 31, 2014, petitioner and her parents saw Dr. Nichter, the neurologist. Id. at 9. Stress was an issue for petitioner. Over the last several weeks, she had such difficulty with stress that she would hyperventilate sometimes and have a 15- and 20-minute period where she was not in control of herself. This exacerbated over the last few weeks. She had a significant sleep dysfunction. Before trying to sleep, she would take a Tylenol PM, which contains Benadryl, and then perhaps a glass of wine a few times a week. Id. She had daily headaches. She did not take any medication for POTS but used various salts. Id. On physical examination,

she had normal gait. Id. at 10. Dr. Nichter's plan was for the family to consider counseling vs. psychiatry. The family was fine with the plan. Id.

Besides Dr. Nichter, Drs. Rheeman and Lindstrom attributed petitioner's problems to stress.

TESTIMONY

Petitioner testified first. Tr. at 14. At the time of the hearing, petitioner was participating in an acting apprenticeship, which was in addition to her college curriculum. Id. at 15. She stated she would love to be an actor and was passionate about the theater. Id. Petitioner said her disability made every day a struggle. Id. She felt as if she were going to pass out three times a day and she watched everything she ate and drank. Id. Petitioner said the headaches were debilitating, but she pushed through every day because acting is what she wants to do and makes her happy, even though she is in pain and struggling. Id. at 15-16. She said it was worth fighting for. Id. at 16. She said there were days when her right knee hurts a lot because of all she has been through relearning how to walk. Id. But, "for the most part we learn as actors that your body is your instrument and you have to take care of it in certain ways, and sometimes it's very difficult to do with all of my medical list of injuries and everything." Id.

Petitioner testified that she feels normal on some days and then, on other days, she has to drag herself out of bed, stop crying, and continue with the day. Id. It changes from day to day. Id. Every day, she wakes with a headache and goes to sleep with a headache. Id. at 17. She constantly watches her blood pressure, her heart, and her head. Id. She has a migraine every day that never goes away. Id. at 19. She has some limb stiffness and pain depending on the weather patterns. Id. at 20. She was wheelchair-bound for seven months because she lost feeling in her legs before she relearned how to walk. Id. She never used crutches before or after the wheelchair. Id. at 21. She would fall down all the time. Id. She still faints, but she fights it. Id. at 24. She has learned certain tricks like clenching her fists or sitting down and then getting back up. Id. She watches her salt and sugar intake. Id. She estimates she has seen about 16 doctors, if not more. Id. at 27. She has a top ten list of people she dislikes the most, and they are the doctors that called her crazy. Id. at 28. She said, "I am not some case. I am a human being. Please listen to me." Id. One of those doctors worked at Boston Children's Hospital and two doctors worked at Johns Hopkins. Id. at 29. She said that the first doctor "with the great idea of me being chronically insanely ill" was Dr. Sobeih, but Dr. Nichter has been her friend throughout this entire process. Id. at 29-30. She said Dr. Nichter has no idea how to help her and no answers, but he is the person she goes to if she has a problem. Id. at 30-31.

Petitioner had strep a few times when she was in elementary school. Id. at 32. She gets rashes occasionally. Id. at 33. She has sworn off all medications except for birth control and occasional ibuprofen. Id. at 34. She told her doctors she wanted to go "all natural" and live without constantly having to take medicine. Id. at 35. She feels medication is not a necessity for her anymore because it was just not doing anything. Id. Her doctors never really had an answer.

Id. at 36. They would all prescribe drugs in their specific field but no miracle drug to help. Id. at 37. She is off all the drugs. They were nothing and did not do very much; they did not help. Id. at 38. The pain in her head was directing vivid dreams when she tried to sleep. Id. She does not sleep very well. Id. She normally wakes more tired than when she went to sleep, and coffee is her "friend." Id. at 38-39. She wakes probably every twenty minutes to an hour and one-half, or at least five times a night. Id. at 39. Most of the time, it is pain that wakes her. Id. Last year, her grades were between 3.7 and 3.8. Id. She said she does pretty well in school and always has. Id. at 39-40.

She just finished playing Maria in Shakespeare's "Twelfth Night" as part of her acting apprenticeship. Id. at 45. She was in rehearsal from 2:00 p.m. to 10:00 p.m. and was very tired, "but it's what I like to do." Id. at 46. Acting is "a different place" and "you fuel yourself with everything . . . to get yourself ready to be in this place." Id. She lifts weights and goes to the gym. Id. at 47. She wants to be the healthiest she can be. Id. She does squats, dead lifts, and other forms of lunges with a bar that has weights on the sides. Id. The bar she uses weighs 35 to 45 pounds, and normally she puts 10 to 15 pounds on each side of the bar. Id. at 48. The 60- to 70-pound weighted bar is on her shoulders while she is doing squats and lunges, and she does three sets of eight to ten repetitions. Id. She alternates between squats and lunges. Id. at 49. At school, she goes to the gym two or three times a week. Id. She will exercise legs one day and arms another day, and leave abdominals, cardiovascular and other things for a third day. Id. at 50. For cardiovascular, she normally uses a stationary bike or possibly the elliptical. Id. When she goes to the gym, she drinks extra water and has some sugar or salt, and she feels good. Id. at 51. When she was in elementary school, she did plays, but she was mostly obsessed with playing soccer. Id. She got into the theater program in high school and did a lot of backstage work. Id. at 52. She has earned ten weeks of a 50-week requirement to earn an Actors' Equity card. Id. at 66-67. Petitioner drinks two to three cups of caffeinated coffee daily. Id. at 84-85.

Petitioner's father testified next. Id. at 107. He is a cardiac surgeon at Albany Medical Center. Id. at 108. Before receiving Gardasil, petitioner was very involved in soccer and had a multitude of fractures with repeated visits to an orthopedic surgeon. Id. at 110. Eight weeks after petitioner's Gardasil vaccination, petitioner had a headache. Id. He thinks petitioner saw a total of 20-25 doctors. Id. at 114. The closest they came to a diagnosis was at Johns Hopkins where Dr. Peter Rowe diagnosed petitioner with chronic fatigue and POTS. Id. at 114. Dr. Nichter, a pediatric neurologist at Albany Medical Center, has been providing continual support to petitioner and her parents. Id. at 117-18. Dr. Nichter could never explain what petitioner's movement disorder was. Id. at 118. He was a cheerleader for petitioner to go to physical therapy and go back to being functional. Id. None of the many medications Dr. Nichter prescribed for petitioner worked. Id. at 119. When petitioner would curl up in a ball and sob from headache pain, she would use oxycodone or hydrocodone. Id. at 119-20.

Petitioner's father focused on Gardasil as the cause of petitioner's complaints when he and his wife heard about a girl, Natalie Rowan,[42] who lives less than two blocks away from them who had almost the identical symptoms petitioner had and had received Gardasil with the same lot number as petitioner received. Id. at 121-20. Petitioner's father never thought petitioner's illness was psychosomatic. Id. at 130.

Petitioner's father prepared a summary of all of petitioner's visits to doctors, but he did not give this summary to Dr. Sandler, the psychiatrist, because petitioner and her parents saw Dr. Sandler before petitioner's father created the summary. Id. at 134. At the time petitioner saw her personal care physician on February 26, 2009 with symptoms consistent with a viral or bacterial infection, petitioner's father wrote a prescription for Cipro for petitioner for presumed sinusitis. Id. at 151-52. Petitioner's father stated petitioner started fainting in the spring of 2009, although his summary of petitioner's medical records states she started fainting in October 2009. Id. at 157-58.

Dr. Yehuda Shoenfeld, an immunologist, testified next for petitioner. Id. at 174. Dr. Shoenfeld has edited and written almost 60 books on different aspects of autoimmune disorders. Id. at 191. His opinion in the instant action is that Gardasil caused petitioner's condition. Id. at 193. Dr. Shoenfeld said at least 12 different doctors saw petitioner before and after the vaccination, and they were perplexed regarding her diagnosis. Id. at 193-94. He stated nobody knew the right diagnosis. Id. at 194. Dr. Shoenfeld said three diagnoses were correct: chronic fatigue syndrome, postural orthostatic tachycardia syndrome or POTS, and undefined connective tissue disease or UCTD. Id. Doctors did not diagnose her with these three diseases before her Gardasil vaccination. Id. Dr. Shoenfeld did not include migraine headaches as part of the three diagnoses because "[m]igraine is a disease by itself." Id. He stated migraine is a neurovascular condition, which does not have an autoimmune etiology. Id. at 194-95.

He said petitioner has lupus anticoagulant, but she does not have antiphospholipid syndrome. Id. at 195. He stated she is at great risk for developing autoimmune diseases, one of which might be antiphospholipid syndrome. Id. Antiphospholipid syndrome or APS appears in 40 percent of cases of systemic lupus erythematosus or SLE. Id. at 196. Petitioner has

[42] Natalie Rowan's father Michael Rowan filed a petition on behalf of his minor daughter on May 3, 2010. When Natalie reached her majority, she became petitioner. Petitioner's counsel in Rowan, Patricia Ann Finn, is the same counsel for petitioner in the instant action (although petitioner at the time of filing the instant action, i.e., who is the current petitioner's father, was pro se until Ms. Finn filed a motion to substitute in order to represent petitioner seven months after the filing of the petition). Petitioner's expert in Rowan, Dr. Yehuda Shoenfeld, is the same expert for petitioner in the instant action. Now-Chief Special Master Nora Beth Dorsey dismissed Rowan. Rowan v. Sec'y of HHS, No. 10-272V, 2014 WL 7465661 (Fed. Cl. Spec. Mstr. Dec. 8, 2014). Petitioner appealed the dismissal. Judge Francis Allegra affirmed the dismissal. 2015 WL 3562409 (Fed. Cl. May 18, 2015 (under seal); reissued June 9, 2015). Petitioner appealed Judge Allegra's affirmance of the dismissal to the Federal Circuit Court of Appeals. The Federal Circuit dismissed the appeal because petitioner failed to file her appellate brief within the time allotted and thus failed to prosecute. No. 15-5119 (Fed. Cir. 2015).

antinuclear antibody or ANA, lupus anticoagulant, and a positive rheumatoid factor. Id. at 197. Doctors did not test for these autoantibodies before petitioner's Gardasil vaccination. Id. at 199. Dr. Shoenfeld believes that if doctors had tested petitioner before her Gardasil vaccination, they would have detected these autoantibodies. Id.

Dr. Shoenfeld testified that antinuclear antibodies frequently occur in chronic fatigue syndrome. Id. He said POTS and chronic fatigue syndrome are overlapping diagnoses and go together quite often. Id. He mentioned that two papers say they are actually the same disease. Id. Dr. Shoenfeld stated petitioner did not have joint pains before her Gardasil vaccination, but she has them now, i.e., swollen knees, ankles, wrists. Id. at 199-200. She also had a rash. Id. at 200. Dr. Michelle Petri, petitioner's rheumatologist, diagnosed petitioner with undefined connective tissue disease because she could not say which one petitioner has. Id. at 201. Dr. Shoenfeld said petitioner could develop rheumatoid arthritis, systemic lupus erythematosus, or scleroderma. Id.

Before Gardasil vaccination, Dr. Shoenfeld said petitioner had headaches, phonophobia, photophobia, some dizziness, and some fatigue. Id. After Gardasil vaccination, she had bad headache, squeezing pain, vertigo, protracted headache, fainting while standing, sleeping disturbances, memory problems, and abdominal complaints, the last three characteristic of chronic fatigue syndrome. Id. at 201-02. Dr. Shoenfeld testified that petitioner's enlarged lymph nodes, fever, fatigue, and dizziness were clinical manifestations compatible with chronic fatigue syndrome. Id. at 204.

Dr. Shoenfeld said that a two-month interval between Gardasil and onset was reasonable. Id. at 206. Autoimmune disease is progressive. Autoantibodies also develop progressively. Id. These autoantibodies may have developed sequentially to each other and not on the same date. Id. at 206-07. Dr. Shoenfeld explained that the adjuvant in the vaccine causes the disease and stimulates the immune system. Id. at 207. The adjuvant remains for weeks in the muscle where the vaccine where the person received the injection. Id. This muscle was biopsied and scientists found aluminum (the adjuvant) there. Id. The purpose of adjuvant is to enhance the immune system. Id. In a vaccinee with a hyperactive immune system, usually a woman because women have a better immune system than men, the vaccinee is more prone to develop autoimmune disease. Id. at 207-08. Adjuvant is an environmental factor causing autoimmune disease. Id. at 208. People involved in sports also are more likely to respond to immunizations. Id. at 209.

Dr. Shoenfeld testified that petitioner's doctors were not aware of the signs and symptoms of very early autoimmune disease that Gardasil induced, and diagnosed petitioner with a psychiatric problem. Id. at 212. Dr. Shoenfeld asked if petitioner's joint pains, rash, and livedo were psychiatric. Id. He also asked if petitioner could induce three different autoantibodies due to a psychiatric problem. Id. at 213. He believed that eventually all petitioner's 12 doctors would have recognized she developed a classic autoimmune reaction after Gardasil. Id. In conclusion, Dr. Shoenfeld said petitioner has classic undefined connective tissue disease, which will most probably evolve into a well-defined autoimmune disease, chronic

fatigue syndrome, POTS, and three different autoantibodies. Id. at 214. Chronic fatigue can be associated with headache. Id.

Dr. Shoenfeld testified that petitioner always had a tendency for autoimmune diseases genetically because her mother has Raynaud's phenomenon. Id. at 215. Even though petitioner did not develop a full-blown autoimmune disease, Raynaud's quite often characterizes patients with different connective tissue disease or precedes connective tissue disease in the future. Id. at 215-16. As for headaches, they are a very common complaint. Id. at 216. Dr. Shoenfeld does not believe petitioner had migraine headaches before Gardasil vaccination. Id. Migraine has nothing to do with chronic fatigue syndrome because migraine is not an autoimmune disease. Id. It is very common in young females, particularly when they start to menstruate and particularly after menstruation. Id.

When petitioner was complaining pre-Gardasil that she had the feeling she was swaying as if on a boat, Dr. Shoenfeld testified that this was not POTS. Id. at 217. He said POTS occurs when someone rises from a recumbent position to the erect position and then experiences a fall in blood pressure and an increase in heart rate (tachycardia), associated with fainting. Id. Dr. Shoenfeld said that petitioner did not have POTS before receiving Gardasil. Id.

In describing two plausible mechanisms of causation in this case, Dr. Shoenfeld said the first is classic molecular mimicry. Id. In Gardasil, in the structure of the viral particles, called the L1, is a portion denoted as numbers 16 and 18, which have molecular mimicry found in many constituents of the human body.[43] Id. at 218. Channels of calcium and potassium, active in our autonomic nervous system, are some of those bodily constituents. Id. The autonomic nervous system adjusts our blood vessels from the supine position, where they are dilated, to the erect position, where they must be squeezed to enable the blood to flow to the brain. Id. Gardasil generates autoantibodies against these constituents into the nervous system, causing malfunction of the system and POTS. Id. at 218-19. Because the adjuvant is in the vaccine, the molecular mimicry is also there.[44] Id. at 219.

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[43] Petitioner filed articles discussing HPV L1: Potential cross-reactivity between HPV16 L1 protein and sudden death-associated antigens by D. Kanduc, 9 J Exp Ther Oncol 159-65 (2011) (P. Ex. 502, also filed as P. Ex. 546) (matches between HPV16 L1 and human proteins which, when altered, are associated with cardiovascular diseases and arrhythmogenic disorders); Quantifying the possible cross-reactivity risk of an HPV 16 vaccine by D. Kanduc, 8 J Exp Ther Oncol 65-76 (2009) (P. Ex. 503, also filed as P. Ex. 547) (host tissues expressed antigens sharing sequences with possible physical consequences such as spinal muscular atrophy, cardiovascular and musculoskeletal abnormalities, and increased risk of coronary artery disease).

[44] Petitioner filed articles relating HPVL1 gene DNA to aluminum adjuvant: Detection of human papillomavirus L1 gene DNA fragments in postmortem blood and spleen after Gardasil vaccination—A case report by S.H. Lee, 3 Advances in Bioscience & Biotechnology 1214-24 (2012) (P. Ex. 30, also filed as P. Ex. 147 and P. Ex. 339) (presence of HPV16 L1 gene DNA in blood and spleen of teenage girl who suddenly died six months after receiving Gardasil; interprets gene fragments not degrading over six months after vaccination to binding to particulate aluminum adjuvant in HPV vaccine); Detection of

Dr. Shoenfeld said the second plausible mechanism is small fiber neuropathy,[45] which is also probably an autoimmune condition, and results from a viral constituent that most probably causes an autoantibody that destroys the ending of fibers in the skin. Id. The regular nerve fibers are not affected and an EMG would be normal. Id. A neurologist will use a biopsy to diagnose small fiber neuropathy. Id. Doctors found that half of patients with chronic fatigue syndrome, fibromyalgia, and POTS had biopsies, which indicated small fiber neuropathy. Id. Petitioner never had a biopsy. Id. at 220. Dr. Shoenfeld concluded there are at least two mechanisms by which Gardasil can cause a malfunctioning of the autonomic nervous system. Id. at 219.

To Dr. Shoenfeld, the fact that petitioner had clinical manifestations and abnormal laboratory findings (lupus anticoagulant, rheumatoid factor, ANA) after Gardasil within two months means Gardasil caused them. Id. at 220. Dr. Shoenfeld means all the adjuvants in Gardasil, not just aluminum, caused the autoimmunity. Id. at 221, 227. He said that his testimony is descriptive of the ASIA syndrome because adjuvants induce autoimmune diseases, i.e., undefined connective tissue disease, SLE, antiphospholipid syndrome, chronic fatigue syndrome, and POTS. Id. at 234. His opinion is that a combination of the effects of the surface antigen of the human papillomavirus, plus adjuvants in general, is the cause of petitioner's illnesses. Id. at 237. He believes petitioner suffers from an autoimmune condition that adjuvants and the virus particles induced. Id. at 238-39. The adjuvant alone could have caused her injuries, but we do not know. Id. at 239. Dr. Shoenfeld said that, in this case, the adjuvant contributed to the condition because, without the adjuvant, there would not have been an enhanced immune response to the viral particles in Gardasil. Id. at 248. In general, he thinks adjuvant alone can cause autoimmunity, but, in this case, a combination of the adjuvant with the vaccine caused petitioner's autoimmune condition. Id. at 249, 256. Petitioner did not have macrophagic myofasciitis syndrome. Id. at 257.

Respondent's counsel realized that Dr. Shoenfeld was not basing his theory of causation on aluminum adjuvant alone causing petitioner's conditions, i.e., he was veering away from his ASIA theory which posits causation from aluminum as a vaccine adjuvant without adding in any other components of the vaccine. Id. at 239-88. Through an extensive series of questions and answers, Dr. Shoenfeld stated he was no longer relying on certain articles dealing with ASIA that petitioner had filed as evidence, but on the other hand, he was relying on other articles. For example, he relied on an article on aluminum injections in mice causing motor deficits and motor

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human papillomavirus (HPV) L1 gene DNA possibly bound to particulate aluminum adjuvant in the HPV vaccine Gardasil® by S.H. Lee, 117 J Inorganic Biochemistry 85-92 (2012) (P. Ex. 31, also filed as P. Ex. 148 and P. Ex. 338) (analysis of 16 Gardasil samples results in residual HPV DNA fragments bound to adjuvant, presumably aluminum, but clinical significance requires further investigation).

[45] "Small fiber neuropathies lead to pain and temperature sensory loss, painless ulceration, injury, and neuropathic joint degeneration . . . ." Peripheral Neuropathy, Vol. 1, at 1146 (eds. P.J. Dyck, et al. 4th ed. 2005). Petitioner was never diagnosed with small fiber neuropathy.

neuron degeneration because that would show aluminum adjuvant can cause small fiber neuropathy even though there is no proof that petitioner has small fiber neuropathy. Id. at 263. At this point, the undersigned stated it was not helpful to prove a mechanism for an illness petitioner did not have. Id. at 264. The undersigned offered to give petitioner time to obtain a biopsy to prove that she has small fiber neuropathy. Id. Dr. Shoenfeld stated the theory of aluminum causing small fiber neuropathy was helpful because it was a "possible theory" in petitioner's case. Id. The undersigned then stated the standard of proof is probability, not possibility. Id. At which point, Dr. Shoenfeld testified that it is probable that petitioner has small fiber neuropathy because half the patients in the paper he was discussing had small fiber neuropathy. Id. at 265-66. The undersigned rejected that petitioner has small fiber neuropathy based on half of the subjects in the paper having small fiber neuropathy. Id. at 266. Petitioner's attorney said she would consider having petitioner undergo a biopsy to determine if she has small fiber neuropathy and would let the undersigned know the next day. Id. at 267-68. Dr. Shoenfeld then said in answer to respondent's counsel's question that he did not know if aluminum adjuvant alone could cause small fiber neuropathy. Id. at 268.

Because Dr. Shoenfeld was no longer advancing an adjuvant only theory as the explanation for how Gardasil can cause various illnesses, respondent opted to no longer rely on the expert testimony of Drs. Cetaruk and Whitton. Id. at 301. The undersigned asked Dr. Shoenfeld if he agreed that there was no physical reason for petitioner to have been in a wheelchair. Id. at 304. Dr. Shoenfeld responded yes. Id. Then he said that chronic fatigue or extreme fatigue might have been the reason petitioner did not walk. Id. He said these are subjective symptoms and we cannot understand how much she was fatigued. Id. He said there are two kinds of fatigue: (1) muscle fatigue, and (2) fatigue from the brain. Id. at 304-05. Many patients with POTS and chronic fatigue syndrome also have depression. Id. at 305. Petitioner had difficulties with smell and taste. He said difficulty with smell is quite often associated with depression. Id. Autoantibodies can be associated with depression. Id. at 307. He and his co-authors injected into mice an antibody from the blood of patients who were depressed and had lupus. Id. Mice in a bucket of water will swim. Id. But the mice who were injected with the antibody from depressed lupus patients did not swim; they floated. Id. Dr. Shoenfeld said they floated because they were depressed. Id. When Dr. Shoenfeld gave the depressed mice smells, such as orange, citron, grapefruit, or lavender, i.e., aromatherapy, they woke up and began to swim. Id. at 308. Dr. Shoenfeld concluded that depression can have an autoimmune origin and is involved with the lack of smell because the antibody binds to the limbic area of the brain, responsible for both emotions and smell. Id. He said women who are depressed do not smell, and they splash too much perfume on themselves. Id. When they stop being depressed, they feel awful for splashing too much perfume on themselves and stop doing so. Id. Relating this to petitioner, Dr. Shoenfeld said that petitioner was depressed and lost her sense of smell. Id. These symptoms joined with her feeling she could not walk and she took to a wheelchair. Id. He said this is a repeated complaint of many patients with POTS. Id. at 309.

In light of Dr. Nichter's note that petitioner walked unaided from the parking lot to his office, but then could only walk with assistance inside his office, the undersigned queried Dr.

Shoenfeld's analysis that petitioner's depression, difficulty smelling, and needing a wheelchair were linked. Id. at 310-11. Dr. Shoenfeld replied that in POTS, as in many autoimmune diseases, the manifestations are not continuous and persistent. Id. at 311. He also said that POTS is not continuous but may be intermittent. Id. The undersigned also queried petitioner's walking probably five miles during a Halloween event, but when Dr. Nichter tested her for weakness, petitioner's response varied. Id. at 312. Because of petitioner's variability in physical testing of strength, Dr. Nichter noted he was going to discuss the results of her examination with petitioner's personal care physician, i.e., Dr. Kennette, and recommend a psychiatric evaluation and a mild mood elevator. Id. Dr. Shoenfeld responded that, eventually, petitioner developed autoimmune phenomena, and he assumes petitioner was at the incubation stage when she had these inconsistent behaviors. Id. at 315. He admitted that mood has a physiological basis. Id. at 316. But, he also said that psychiatric manifestations have an organic source in the brain. Id. at 317. He said different chemicals in someone's brain can affect his or her mood, and one of the examples is smell, which can affect mood. Id. If smell is affected, so is taste. Id. at 318.

Dr. Shoenfeld stated that petitioner does not fulfill the criteria for systemic lupus erythematosus because she does not have four out of eleven criteria; she has three out of eleven. Id. at 318-19. He does not think petitioner has SLE, but she has a good chance of developing SLE in the future. Id. at 319. She could develop antiphospholipid syndrome. Id.

On cross-examination, Dr. Shoenfeld stated petitioner does not have acute cerebellar ataxia. Id. at 347. He has between 50 and 100 chronic fatigue patients and treats almost none of them with immune suppressants. Id. at 370, 372. He has between 10 to 20 POTS patients, most of whom overlap with chronic fatigue. Id. at 372-73. He does not treat any of them with immunosuppressants because they have severe side effects. Id. Dr. Shoenfeld recommended vitamin D in large doses, i.e., 2,000 units per day, to prevent or slow down the process of autoimmune disease. Id. at 389. For molecular mimicry to occur, at least three weeks and sometimes more weeks are necessary to generate autoantibodies. Id. at 375. Then the autoantibodies need to increase in titer to reach and penetrate the target organ. Id. This takes weeks. Id. An article by Arbuckle[46] about military personnel who developed lupus showed that their blood, taken 10 years earlier before they became symptomatic and which was still preserved, contained autoantibodies of anti-CCP and rheumatoid factor. Id. at 387, 392. To explain why it could take 10 years for someone with autoantibodies to manifest autoimmune disease, Dr. Shoenfeld stated sometimes the process is prolonged and sometimes a person needs another hit. Id. at 388. The slow process is called incubation time. Id. This is why petitioner is at great risk of eventually developing autoimmune disease – she has three autoantibodies. Id. at 389.

Dr. Shoenfeld set the interval between petitioner's second Gardasil vaccination and the onset of her POTS at two months. Id. at 392. Dr. Shoenfeld stated we can never know if

[46] Arbuckle, M.R., et al., Development of Autoantibodies before the Clinical Onset of Systemic Lupus Erythematosus, 349 NEJM 1526-33 (2003). P. Ex. 334.

petitioner had a positive rheumatoid factor, lupus anticoagulant, and elevated ANA before her Gardasil vaccinations because she was not tested for them, but she was genetically prone to develop them. Id. at 393. He said petitioner is part of a family with autoimmune disease. Id. at 395. For example, petitioner's mother has Raynaud's phenomenon. Id. In addition, petitioner's maternal grandmother has thyroid disease. Id. Most thyroid disease is autoimmune. Id. at 396. To Dr. Shoenfeld, the first "hit" (i.e., cause) is genetics. Id. at 395. The second "hit" for autoimmune disease could be a vaccine, silicon implant, infections, etc. Id. at 395-96.

Dr. Max Wiznitzer testified for respondent. Id. at 410. He is a pediatric neurologist with patient care and teaching responsibilities. Id. at 411-12. He has had patients with POTS, chronic fatigue syndrome, autoimmune disease, and headache disorders. Id. at 415, 416, 418, 419. He sits on the editorial boards for Lancet Neurology and the Journal of Child Neurology. Id. at 423.

Dr. Wiznitzer's opinion is that Gardasil did not cause petitioner a neurological injury. Id. at 425. In June 2007, petitioner had a headache lasting for at least a week, associated with dizziness, and light and noise intolerance, but no vomiting or fever. Id. On February 21, 2009, petitioner had a bad headache that tended to persist, with noise intolerance, similar to her complaint in 2007. Id. Cold symptoms, nausea, and dizziness occurred a week before it, consistent with an acute viral infection. Id. at 425-26. Petitioner continued to have headaches from that time forward and went to an emergency room in early March for an evaluation, involving a neurologist. Id. at 426. She had her first brain MRI in 2007 and her second brain MRI in 2009 because of her headache. Id. She continued to have headache, vertigo, and photophobia that caused daily dysfunction. Id.

Dr. Wiznitzer testified that petitioner's neurologic examination did not show any abnormalities of strength or tone. Id. She reported some walking issues and reduced her activities because of the constant headache complaints. Id. By September, she was having fainting spells, seeing black dots in front of her eyes. Id. Dr. Peter Rowe diagnosed petitioner with POTS in August 2010, after a cardiology evaluation in December 2009. Id. at 427. Petitioner testified that she continues to have headache complaints and some lightheadedness and dizziness intermittently. Id. Her blood tests showed a positive ANA and rheumatoid factor, and the equivalent of a lupus anticoagulant. Id. At Dr. Rowe's request, petitioner had an extensive battery of tests against antibodies, including against the P/Q calcium channel, acetylcholine receptor, and various other things, all of which were negative. Id. Petitioner's current diagnosis is POTS and chronic daily headache syndrome. Id. at 428.

Petitioner had a viral illness on February 26, 2009. Id. This was about 11 weeks after her second Gardasil vaccination. Id. at 429. Her cold was not due to the vaccination. Id. Petitioner had had a prior headache event in 2007, which was unrelated to any vaccination. Id. Acute viral illnesses can trigger chronic daily headaches and transform an individual who had episodic headaches into having chronic daily headaches. Id. On March 6, 2009, petitioner went to the emergency room at Albany Medical Center. Id. at 430. The record said that petitioner's Romberg was negative, but she appeared to overcorrect with loss of balance. Id. Her gait was

narrow-based but ataxic with her requiring assistance in order to walk without falling. Id. The diagnosis was headache and ataxia. Id. Dr. Wiznitzer disagreed that petitioner had ataxia. Id. at 431. Dr. Nichter, a pediatric neurologist, saw petitioner in the ER on the same date, and noted that petitioner had a normal gait. Id. Dr. Nichter wrote that she had a tandem gait with an ever so slight wobble. Id. She hopped on one foot and two feet, and squatted without difficulty. Id. His diagnosis was that petitioner did not have concerning ataxia or vertigo. Id.

Dr. Wiznitzer finds it significant that petitioner did not have ataxia on March 6, 2009. Id. at 432. Dr. Wiznitzer said that the ER doctor did not know as much about ataxia as Dr. Nichter, a pediatric neurologist. Id. Dr. Wiznitzer testified it is not plausible that a person with significant ataxia will have a narrow base to her gait. Id. Dr. Wiznitzer then stood up in the courtroom and demonstrated what he was saying. Id. at 433. Normally, people typically stand with a narrow base, meaning with their feet maybe six inches to a foot apart. Id. A person with ataxia, i.e., unsteadiness, looks like he is drunk. Id. A drunk person cannot stand with his feet together. Id. That is why the police test a driver by having him walk a line, which is a narrow base. Id. A drunk driver will stand with his feet about two feet apart as he walks, and is unsteady and will typically fall over. Id. at 433-34. If, however, someone walks with a narrow base and yet is unsteady, that is not ataxia. Id. at 434.

Moreover, Dr. Wiznitzer testified, ataxia does not come and go. Id. If petitioner truly had ataxia on March 6, 2009, it would not be there for the emergency room doctor and gone when Dr. Nichter examined her. Id. Dr. Shoenfeld postulated that petitioner's ataxia was immune-mediated, but if it were, the ataxia would not have gone away. Id. Dr. Wiznitzer's opinion is that petitioner never had ataxia. Id. at 435. Dr. Wiznitzer called what petitioner had a gait disturbance. Id. In 2007, petitioner also had a gait disturbance, where she needed support when she was not feeling well. Id. at 435. Petitioner's episode on June 6, 2007 could be due to ataxia or vertigo when doctors diagnosed her with a migraine headache since either ataxia or vertigo is a known accompaniment of migraine. Id. at 436. Dr. Wiznitzer testified that this March 6, 2009 emergency room record was the only place in petitioner's medical records where a doctor (a non-neurologist) mentioned ataxia, and none of her neurologists stated she had ataxia. Id. at 437.

Dr. Wiznitzer turned to an August 2009 physical therapy record, which stated petitioner's physical presentation with immobility continued to be incongruent with objective measurements. Id. He said that note was consistent with the doctors' diagnosis of petitioner with astasia-abasia. Id. The way petitioner moved was not consistent with the features of her actual exam. Id. at 438. People with astasia-abasia maintain a narrow base when they walk and appear to fall or bump into things, but never suffer any serious injuries. Id. They may have giveaway weakness of the extremities so that, as they walk, suddenly, their knees seem to give out from under them. Id. Astasia-abasia is not a gait that is physiologic in nature. Id. Astasia-abasia does not look like ataxia. Id. It also does not look like dystonia, rigidity, chorea, or any of the other movement disorders that neurologists typically see. Id. Dr. Wiznitzer testified that there is no doubt that petitioner had astasia-abasia. Id. at 439. Dr. Sobeih in Boston diagnosed petitioner with astasia-

abasia on May 4, 2009. Id. Dr. David Cornblath from Johns Hopkins diagnosed petitioner with astasia-abasia. Id. Petitioner's treating pediatric neurologist Dr. Nichter diagnosed petitioner with astasia-abasia on May 28, 2009 and July 6, 2009. Id. Dr. Argoff was also concerned about petitioner's gait because he could not categorize it. Id. at 441.

Dr. Wiznitzer and other neurologists get patients all the time for evaluation of their gait to determine if their gait has an organic origin or is symptomatic of a conversion disorder. Id. at 439-40. The latter is a disorder of the mind. Id. at 440. Astasia-abasia does not indicate a neurologic injury, but is a psychological disorder, part of the somatoform disorders in the Diagnostic and Statistical Manual of Mental Disorders ("DSM"). Id. It is a problem with standing and/or walking that no organic problem can explain, which means the individual has no identifiable problem with strength, tone, coordination, or sensation. Id. The article to which Dr. Shoenfeld referred during his testimony (Ex. 504, a case report of acute cerebellar ataxia 12 days after HPV vaccination) is irrelevant to this case because petitioner did not have a chronic or acute ataxia syndrome, and, in any event, a case report does not prove causation. Id. at 442, 443.

Dr. Wiznitzer disagreed with Dr. Shoenfeld that petitioner lost her sense of smell. Id. at 443. The medical records state that petitioner complained certain smells bothered her. Id. Another record says altered taste and smell, not lost taste and smell. Id. 444. Petitioner complained that food tasted weird, and was either too salty or too bitter. Id. at 446. Petitioner said smells annoyed her. Id. Another record states petitioner had a heightened sense of smell and taste. Id. at 447. She found many tastes noxious. Id. Dr. Shoenfeld used loss of smell as the reason to refer to a mouse model to hypothesize an antibody mechanism, but Dr. Wiznitzer said this has no relation here because petitioner did not lose her sense of smell. Id.

In November 2009, petitioner saw Dr. Nichter, who performed a neurological examination. Id. at 447-48. Petitioner was quite variable as to weakness. Id. at 449. At times, she was weaker on the left than on the right side, but the weakness was inconsistent. Id. Petitioner could barely walk during the examination, but when she came from the parking lot, she walked to the waiting room without assistance. Id. Petitioner could not jump on two feet without some assistance, but at other times, she was able to jump perfectly fine. Id. Dr. Wiznitzer called this a waxing/waning examination. Id. He stated this was clearly not ataxia. Id. Moreover, when someone manifests waxing/waning strength and she does not have myasthenia gravis (and even with myasthenia, someone would need a nap or medication to regain strength), then the only explanation is conversion disorder. Id.

Dr. Wiznitzer defined POTS as consisting of complaints of dizziness, and lightheadedness, with perhaps seeing spots before one's eyes. Id. at 450. It occurs when someone goes from the lying position to the standing position. Id. If the patient lies down, he or she feels much better. Id. POTS is associated with an increase in heart rate. Id. The person feels lightheaded, dizzy, faint, a little nauseated, maybe has spots before his or her eyes, due to inadequate blood flow to the brain. Id. at 452. Generally, people do not pass out, but can have near syncope. Id. Petitioner herein never had a tilt table test. Id. at 453. The undersigned then

asked petitioner's father if petitioner had ever had a tilt table test and he said no. Id. He said that Dr. Peter Rowe said he was confident just from his examination of petitioner that she had POTS. Id. Dr. Wiznitzer accepts that petitioner has POTS. Id. at 454. POTS is a problem with neurological control of circulation. Id. Some cases of POTS are immune-mediated. Id. A small number of POTS patients have ganglionic isotope choline receptor antibodies. Id. However, petitioner was tested for those ganglionic antibodies and the result was negative. Id. Petitioner had no measurable level of ganglionic isotope choline receptor antibodies. Id. Neurologists can diagnose POTS. Id.

Dr. Wiznitzer sees POTS patients in his practice. Id. at 455. Deconditioning can cause POTS. Id. POTS can also happen after an acute illness, after surgery, and if someone is lying or sitting around and becomes deconditioned. Id. If someone develops POTS from an illness, it can be concomitant with the illness or within a week or two after it. Id. at 455-56. Dr. Rowe noted in his record that petitioner did not walk much until August 2009. Id. at 457. Dr. Wiznitzer's opinion is that petitioner's onset of POTS was when she reported fainting spells in September or October 2009. Id. at 458. Petitioner did complain in March and April 2009 about headaches and gait problems, but her gait was actually astasia-abasia, which does not reflect poor coordination. Id. Petitioner's complaint in March and April 2009 was not due to weakness. Id. However, if we consider petitioner's complaint of lightheadedness as due to POTS, her onset of POTS might have been in March or April 2009. Id. at 459. She did not have POTS in June 2007 when she had an episode of dizziness. Id. at 459-60.

Dr. Wiznitzer stated that his POTS patients do not normally present with headaches. Id. They normally present with complaints of dizziness, lightheadedness, and weakness. Id. Later, they may start complaining of headaches. Id. He thinks petitioner's headaches were related to her viral illness. Id. One can have headaches with chronic fatigue syndrome. Id. at 461. Dr. Wiznitzer has no opinion about the onset of petitioner's chronic fatigue syndrome. Id.

In discussing Dr. Shoenfeld's hypothesis that there are amino acid sequences on the L1 protein of HPV, specifically HPV16, which set off molecular mimicry in the vaccinee, Dr. Wiznitzer said he disagreed. Id. at 461-62. Dr. Shoenfeld's theory assumes that a five-amino acid sequence is sufficient to cause an antibody to form. Id. at 462. But the sequence is too small to cause antibody formation. Id. Rather, one would need at least 10-15 amino acids to have a chance to form an antibody. Id. at 463. Even a five-amino acid sequence forming an antibody does not equal a functional antibody that harms someone. Id. We have numerous antibodies in our blood which are detectible, but do not cause problems. Id. Dr. Shoenfeld also assumes that this hypothetical antibody can get to the target of interest and, if it does, that it can actually bind to the target of interest. Id. The assumption also is that if the antibody binds to the target, it will disrupt the function of the molecule and that this molecule has anything to do with petitioner's problems. Id. Dr. Wiznitzer testified that Dr. Shoenfeld's hypothesis is conjecture built upon speculation. Id. at 463-64.

Dr. Wiznitzer testified that Dr. Shoenfeld testified about a CACNA1C gene product, quoting from Kanduc's paper. Id. at 464. This gene product helps make a calcium channel known as an L voltage-gated calcium channel, which is calcium channel 1.2. Id. This calcium channel is not present in the peripheral autonomic nervous system. Id. There are different channels in the peripheral autonomic nervous system. Id. Since the L voltage-gated calcium channel, i.e., calcium channel 1.2, is not present in the peripheral autonomic nervous system, the antibody cannot attack it. Id. That channel is located in the brain. Id. at 465. There is no peripheral nerve involvement or peripheral autonomic nerve involvement. Id. at 466, 467.

Dr. Wiznitzer testified that Dr. Shoenfeld's other hypothesis was that this hypothetical antibody would target a calcium channel in the heart and cause POTS. Id. at 480. Dr. Wiznitzer does not know any good biological model to support that hypothesis. Id. When that calcium channel becomes dysfunctional, the person develops true arrhythmias and heart disturbances. Id. at 481. Brugada syndrome[47] is tachyarrhythmia[48] with the risk of sudden death, not a little bit of increase in heart rate when someone stands. Id. If a targeted calcium channel in the heart caused cardiac dysfunction, the blood pressure would be low and the person would not have POTS. Id. Because of the low blood pressure, it would not matter whether the person was standing or lying down. Id. at 482.

Dr. Wiznitzer explained petitioner's reeling back and forth as the result of a combination of lightheadedness from the discomfort of her headache and the headache. Id. at 471. Later on, she had the POTS-type of complaint, which made her feel a bit unsteady. Id. We know she had astasia-abasia, which is conversion disorder. Id. Depression does not cause the kind of gait petitioner had. Id. at 472. Dr. Wiznitzer agreed with Dr. Shoenfeld that petitioner had a change in her mood, i.e., depression, which sent her to a wheelchair for seven months. Id. Dr. Wiznitzer has patients who are depressed and stop their activities. Id. They sit in their room all the time. Id. Their mood heightens whatever somatic complaints they have. Id. at 463. However, petitioner's depression was not immune-mediated in this case. Id. Someone with a conversion disorder does not have frank anxiety or depression. Id. at 474. A conversion disorder exists because of some psychological process that is so bothersome to someone that she manifests it in a different way, e.g., through gait disturbance. Id. at 474-75. This decreases the psychic pain associated with confronting the issue she does not want to confront. Id. at 475. That is the primary gain for conversion disorder. Id. at 476. The secondary gain for conversion disorder is to get a lot of attention. Id. Dr. Wiznitzer believes that petitioner's chronic daily headache is due to stress because when she returned to school, her headaches increased. Id. at 477. There has to be a psychological component to petitioner's headaches. Id. at 478.

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[47] Brugada syndrome is "a type of ion channelopathy characterized by sudden, idiopathic ventricular fibrillation in an apparently healthy person, often resulting in death *(sudden adult* or *sudden arrhythmia death syndrome)*. It is autosomal dominant and occurs most often in males of Southeast Asian origin." Dorland's at 1823.

[48] Tachyarrhythmia is "any disturbance of the heart rhythm in which the heart rate is abnormally increased, usually to greater than 100 beats per minute in an adult." Dorland's at 1867.

Since Dr. Shoenfeld testified that petitioner might have small fiber neuropathy, Dr. Wiznitzer defined it. Id. at 484. Small fiber neurons are unmyelinated, and deal with touch, temperature, and autonomic functions such as sweating. Id. Petitioner's physical examination did not have small fiber neuropathy features present. Id. at 486. In POTS, a subset of patients can also have small fiber neuropathy. Id. at 487. If someone had an antibody that attacked the heart, the person would have heart damage. Id. at 489. Medical literature has not reported that POTS is associated with primary cardiac dysfunction. Id. Dr. Wiznitzer has had patients with cardiomyopathy and doctors have not diagnosed them with POTS. Id.

Referring to petitioner's exhibit 425, a letter to the editor concerning someone who had POTS two weeks after a Gardasil vaccination,[49] Dr. Wiznitzer stated that a temporal association after a vaccination does not imply causal association. Id. at 491. Articles that compare computer models of proteins in vaccines to human proteins are not taking into account the configuration of the protein in the human being. Id. at 494. Homology on a two-dimensional plain means nothing. Id. at 495-96. We do not know if the components of human papillomavirus vaccine, e.g., L1 protein, generate an antibody and, if they do, whether the antibody does anything. Id. at 496.

Dr. Wiznitzer commented on the case report Dr. Shoenfeld and coauthors published about petitioner's case, filed as Exhibit 470.[50] Id. at 502-03. Dr. Wiznitzer said the case report was not an accurate factual synopsis of petitioner's history because it omitted her conversion

[49] Postural tachycardia syndrome after vaccination with Gardasil by S. Blitshteyn, 17 Eur J Neurol 7:e52 (2010); doi:10.1111/j.1468-1331.2010.0321.x. Dr. Blitshteyn writes that an autoimmune etiology for POTS has been implicated in about 14 percent of patients with POTS after detection of ganglionic acetylcholine receptor ("AChR") antibody. Id. at 1.

[50] Petitioner filed a draft of a case report as Ex. 470, Appendix B. Manuscript file (Dr. Shoenfeld referred to this manuscript in his response to respondent's expert Dr. Rosé's expert report). Dkt entry no. 53. The manuscript is a draft of a case report entitled Postural Orthostatic Tachycardia With Chronic Fatigue After HPV Vaccination as Part of the "Autoimmune/Auto-inflammatory Syndrome Induced by Adjuvants": Case Report and Literature Review by L. Tomljenovic, S. Colafrancesco, C. Perricone, and Y. Shoenfeld [petitioner's expert herein]. The authors sent the draft to the Journal of Investigative Medicine High Impact Case Reports. P. Ex. 471 is an e-mail from the editorial office of the Journal of Investigative Medicine High Impact Case Reports, dated January 16, 2014, saying the journal had accepted the draft for publication. Dkt entry no. 54. The Journal of Investigative Medicine High Impact Case Reports is an open-access journal from the American Federation for Medical Research published by SAGE. afmr.org/JIMHICR.cgi (last visited: Jan. 25, 2017). The published version of Ex. 470 is available at doi:10.1177/2324709614527812. The "Declaration of Conflicting Interests" section at the end of the case report states "the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Y. Shoenfeld is currently providing expert testimony in cases involving adverse reactions to the HPV and other vaccines in the US National Vaccine Injury Compensation Program (including this case)." Id. at 6. The "Authors' Note" above the "Declaration of Conflicting Interests" states that petitioner gave her informed consent to present her case in the case report. Id.

disorder and astasia-abasia. Id. at 503. The case report says "gait disturbance," which is too vague since petitioner did not have true leg weakness according to a neurologic examination. Id. at 506. There was nothing wrong with her motor system, her sensory system, or her balance system. Id. Dr. Wiznitzer disagrees with Dr. Sandler's opinion that petitioner did not have psychosomatic symptoms. Id. at 508-09. Dr. Sandler's conclusion flies in the face of all the other information in the medical records, including that she had depression. Id. at 509. It does not mention mood disturbance either. Id. at 503. Dr. Wiznitzer said Dr. Shoenfeld did not put all the facts in his case note. Id. He quoted Dr. Sandler, the psychiatrist, saying petitioner did not have psychosomatic symptoms, but ignored the conclusions of those who did not agree with him. Id. When someone writes a case note, he should put all the facts in, not just the facts with which he agrees. Id.

Dr. Wiznitzer's opinion is that HPV vaccine had nothing to do with petitioner's ailments. Id. at 504. She developed a chronic daily headache after an acute febrile illness in February 2009. Id. Later, she developed POTS. Id. She had a conversion disorder manifested as astasia-abasia. Id. Then doctors tested her blood and found rheumatologic abnormalities. Id. Doctors later diagnosed her with chronic fatigue syndrome. Id.

Dr. Stephen J. McGeady, a retired immunologist who now practices pediatrics one and one-half days a week, testified second for respondent. Id. at 543-44. He also lectures medical students in allergy and immunology. Id. at 546. He is board-certified in pediatrics, allergy and immunology, and diagnostic laboratory immunology. Id. at 548. His research interest centers around the field of immune deficiency. Id. at 549. His opinion is that petitioner's HPV vaccinations on August 26, 2008 and December 3, 2008 did not injure her. Id. at 555. He disagrees with Dr. Shoenfeld's analysis because, if petitioner had reacted abnormally to HPV vaccination, he would expect inflammatory mechanisms to be present that would cause tissue damage. Id. at 558. For instance, her erythrocyte sedimentation rate ("sed" rate), C-reactive protein ("CRP"), and platelet count should have risen. Id. Sometimes the complement components and white cell count could also be elevated. Id.

Dr. McGeady defined chronic fatigue syndrome as resulting in various aches and pains, including headache, and a general malaise. Id. at 559. Doctors do not treat chronic fatigue patients with immune system suppressants. Id. at 559-60. Chronic fatigue syndrome is not an autoimmune disease. Id. at 560. Doctors also do not treat POTS patients with immune system suppressants. Id. at 560. Migraine headaches are not an immune disease. Id. at 561. Doctors do not treat migraine headache patients with immune system suppressants. Id.

Dr. McGeady said petitioner's first symptoms, a sore throat, headache, and low-grade fever, suggested she had a virus. Id. at 562. Petitioner's first test on March 3, 2009 was a complete blood count ("CBC"), consisting of measurements of hemoglobin, hematocrit, the white blood cell count, and a differential. Id. at 563. The results did not show any markers of inflammation or heightened immune response. Id. Petitioner's three tests for Lyme disease were negative. Id. at 566.

Dr. McGeady thinks that petitioner was positive for antinuclear antibodies ("ANA") as early as 2004 (years before her HPV vaccinations in 2008) because an elevated ANA would affect the results of her Epstein-Barr virus ("EBV") nuclear antigen test administered April 5, 2004, the results of which were "weakly positive at 1 to 10." This result was identical to the result of the EBV nuclear antigen test done March 3, 2009 (after petitioner received two HPV vaccinations in 2008). Id. at 571-72. Petitioner's weakly positive EBV nuclear antigen result conflicted with the negative results for current or past infection with EBV in the negative IgM and IgG tests. Id. at 566-67. Those negative tests would indicate that she had never been exposed to EBV. Id. at 567, 568. Dr. McGeady said his analysis of these test results is consistent with Dr. Shoenfeld's citation of the Arbuckle article that ANA can be positive for very long periods of time before the onset of clinical symptoms. Id. at 572. Arbuckle discussed the testing of blood of former servicemen before they had clinical onset of rheumatoid arthritis.[51] Id. Dr. McGeady continued his explanation of the significance of the weakly positive EBV nuclear antigen test four years before petitioner received HPV vaccine. Id. at 573. ANA, being antinuclear antibody, and EBV nuclear antigen share some nuclear components; therefore, a positive ANA could have confounded the test results of the EBV nuclear antigen. Id. Dr. McGeady cannot think of any other reason for the confounding of the EBV test results, with IgM and IgG testing negative for EBV exposure, but EBV nuclear antigen testing weakly positive. Id.

Dr. McGeady continued with an analysis of the April 6, 2009 blood tests, which showed a normal CBC and C-reactive protein, meaning that petitioner did not have inflammation. Id. at 575, 576. The liver produces C-reactive protein and the production increases when there is inflammation. Id. at 576. On April 6, 2009, petitioner's ANA test result was elevated at 1 to 640 with a speckled pattern. Id. at 577. Petitioner had a negative result of testing for DNA anti-double stranded antibodies, which is a test for lupus. Id. at 577, 578. Under the direction of the immunologist Dr. Meuwissen, petitioner was tested for IgG, IgM, IgA, and IgE on June 30, 2009 and the test results were normal. Id. at 578, 579. On June 30, 2009, petitioner's ANA test result was the same as April 6, 2009. Id. at 580. Further testing showed that petitioner is not immune-deficient. Id. at 583. Petitioner had a normal result to testing of complement, which showed she did not have antibody-mediated inflammation. Id. at 584, 585. On September 16, 2009, petitioner's cerebrospinal ("CSF") fluid was tested and the result did not reveal an inflammatory process in the central nervous system. Id. at 587.

[51] Arbuckle and his co-authors examined serum samples from 130 patients who were or had been in the military and who had systemic lupus erythematosus. P. Ex. 334, at 3. They found that the time from detection of a positive antinuclear antibody to clinical symptoms in 78% of the patients was 9.2 years, although the amount of time ANA was present was limited by the earliest date of the blood sample. Id. They conclude that some autoantibodies, such as ANA, usually precede the onset of SLE by many years. Id. at 6. They also note that ANA are relatively common in normal persons who have never had clinical symptoms of rheumatic disease. Id.

Dr. Kremer, petitioner's second neurologist, ordered testing on October 27, 2009. Id. at 588. Petitioner's CBC and sedimentation rate were normal. Id. at 589, 592. Petitioner did not have significant inflammation. Id. at 593. On September 12, 2011, petitioner's rheumatoid factor was slightly elevated at 22, when the laboratory's range of normal was less than 20. Id. at 595, 596. Since petitioner previously had a positive ANA and lupus anticoagulant, the finding of a slightly elevated rheumatoid factor is not surprising since it is another autoantibody. Id. at 596. The finding indicates that petitioner was making autoantibodies and is at least a candidate for some sort of autoimmune condition. Id. at 597. The result of petitioner's test for antibody to ganglion neurons was zero, which does not suggest that her POTS was autoimmune. Id. at 600.

Dr. McGeady proceeded to discuss one of the two Kanduc articles (P. Ex. 502) submitted into evidence. Id. at 602. Kanduc and her co-authors looked at a sequence of five amino acids and found that the L1 protein had 34 pentamers in the viral capsid protein, which matched similar sequences in the human proteome. Id. at 602-03. But this was just a computer match. Id. at 603. Of the 34 matches, five amino acids were identical. Id. Dr. McGeady agrees with Dr. Wiznitzer's criticism of the Kanduc paper because it was a two-dimensional, rather than a three-dimensional, homology. Id. Dr. McGeady explained that where an antibody binds is called an epitope. Id. There are two types of epitope, one linear and the other conformational. Id. Amino acids are not present in nature in a linear configuration, like a string with lights on it. Id. at 603-04. In nature, amino acids are arrayed in loops and twisted around one another in unusual shapes. Id. at 604. An antibody can be directed against a linear epitope or a conformational epitope (which consist of the tips of two or three of these loops). Id. The fact that five amino acids in the L1 protein match five amino acids in the human proteome says absolutely nothing about the type of configuration where they are found in either the L1 protein or the human proteome. Id. A scientist has to do x-ray crystallography studies to determine these appropriate configurations and the Kanduc study does not report that the authors did this. Id. The Kanduc authors discuss the astronomical odds of arriving at a match. Id. at 605. Dr. McGeady testified that a five-amino acid sequence would not be sufficient to induce homology. Id. at 606.

Dr. McGeady said that the beginning of developing antibody response against a cell protein is three days. Id. at 609. The primary response occurs in five or six days with IgM, which will fade, and then one gets IgG, and after 14 days, that fades. Id. at 610. A person would manifest a response depending on whether this is the first time the person is exposed to this cell protein or this is a recall response, i.e., a secondary response. Id. A primary response would occur in two weeks because it takes that long to get a significant titer of antibodies. Id. Dr. McGeady would expect the furthest response to be three to four weeks for an antibody-mediated response to a neoantigen. Id. at 611. He does not think an 11-week onset of symptoms is likely. Id. at 612. He would be suspicious of anything occurring beyond four weeks. Id. at 613.

Dr. McGeady testified that if a person received a vaccine he had previously received, the onset of symptoms would be greatly accelerated. Id. The antibody production would be well on its way in three or four days and you would expect clinical symptoms sooner than four weeks.

Id. at 614. His opinion is that HPV vaccine was most unlikely to have played any role in petitioner's alleged injuries. Id. at 615. On cross-examination, Dr. McGeady admitted that petitioner's positive ANA, positive lupus anticoagulant, and positive rheumatoid factor indicate an autoimmune disorder. Id. at 617-18.

Responding to the undersigned's question to Dr. Shoenfeld regarding Dr. McGeady's testimony that petitioner's EBV nuclear antigen pre-vaccination was weakly positive as a consequence of an elevated ANA, Dr. Shoenfeld stated he disagreed. Id. at 626. Yet, Dr. Shoenfeld's stated, "Antinuclear antibodies can cause [a] false positive of EB virus," which is exactly what Dr. McGeady said. Id.

Dr. McGeady later stated that since petitioner's EBV IgG and IgM were negative on testing on April 5, 2004, she could not have had an Epstein-Barr infection to account for the positive EBV nuclear antigen result on April 5, 2004. Id. at 734. The positive EBV nuclear antigen in 2004 in the absence of EBV infection supports Dr. McGeady's opinion that her positive EBV nuclear antigen in 2004 reflected her having a positive ANA in 2004. Id. at 735.

On cross-examination, Dr. McGeady said it was quite difficult to say what caused petitioner's undifferentiated connective tissue disease because he does not believe anyone knows that. Id. at 744-45. Petitioner does have a family history to support that disease. Id. at 745. He agrees with Dr. Wiznitzer that petitioner had elements of a conversion reaction. Id. As for Dr. Sandler, the psychiatrist who saw petitioner a couple of times, and his professional opinion that petitioner did not have psychosomatic disorder, Dr. McGeady stated, in comparing Dr. Sandler to Sigmund Freud, who saw patients for months before he figured out what conflict they had:

> [T]o go from that [seeing a patient for months] to a single visit or a visit or two or three in which the patient was seen and to say, oh, well, there's nothing there, I think that's a little unrealistic in face of the findings that have been presented in this case.

Id.

There followed a discussion of petitioner's negative testing for acetycholine receptor ("AChR"), ganglionic neuronal antibody which resulted in zero. Id. at 750. Subsequent testing for AChR, ganglionic neuronal antibody resulted in less than or equal to 0.02. Id. at 751. Dr. McGeady testified that these negative results strongly suggest that petitioner's POTS was not autoimmune. Id.

Dr. Shoenfeld then stated that Dr. McGeady was incorrect because there exist other autoantibodies, for which petitioner was not tested. Id. at 752. Dr. Shoenfeld said the fact that the antibodies for which petitioner was tested were negative does not exclude autoimmunity. If they had been positive, her POTS would have been autoimmune. The fact that the tests were

negative does not exclude autoimmunity. Id. In POTS, there are at least six or seven different autoantibodies. Id. at 753. Petitioner was not tested for them. The following colloquy occurred:

> THE COURT: All right. So, what we have is that the one test for antibodies, which was ganglionic neurons, was tested twice and was negative, and so we have no proof that she has autoimmune POTS, because the other tests were not done.
> DR. SHOENFELD: Yes.
> THE COURT: Would you agree with that?
> DR. SHOENFELD: Yes. It does not exclude autoimmunity.
> …THE COURT: What you do not want to hear is she doesn't have autoimmune POTS, because all of the testing that could have been done wasn't done, but I'm saying to you I have no proof that she does have autoimmune POTS. All I have is proof that there is no antibody to ganglionic neurons because the testing was negative. Would you agree, Doctor?
> DR. SHOENFELD: I agree.

Id. at 753-54.

Dr. Carlos D. Rosé, a pediatric rheumatologist, testified third for respondent. Id. at 645. He is the chief of pediatric rheumatology of the Division of Pediatric Rheumatology at Thomas Jefferson University. Id. at 647. He treats patients with undifferentiated connective tissue disease. Id. at 648. He also trains medical students, residents, and fellows. Id. at 649.

Dr. Rosé's opinion in this case is that Gardasil vaccine had no relationship with petitioner's rheumatic condition. Id. at 659. He stated that on April 2, 2008 (pre-vaccination), petitioner visited her orthopedist, Dr. Richard Uhl, who had been following her for hand trauma with persistent pain. Id. at 659-60. He was suspicious of petitioner's having reflex sympathetic dystrophy, which is a form of regional limb pain related to amplified pain, and recommended she take Neurontin for pain. Id. at 660. An MRI of petitioner's upper extremity was done. In addition, Dr. Rosé saw a bone scan done which showed petitioner had decreased profusion in that hand. To Dr. Rosé, this signifies that petitioner had a tendency to develop chronic and amplified pain in 2008. Id. Petitioner's tendency to amplify pain occurred before petitioner's first Gardasil vaccination on August 26, 2008. Id. at 660-61.

Dr. Rosé stated amplified pain syndrome is an umbrella term used to refer to children and adults who suffer a disproportionate amount of pain after minor trauma. Id. at 661. It is also specifically well known as reflex sympathetic dystrophy. Individuals with reflex sympathetic dystrophy tend to get fibromyalgia at an older age. Id. Reflex sympathetic dystrophy is characterized by localized swelling, changes in the color of the skin, changes in temperature both perceptional and by examination, and by allodynia, which is a pain response to stimuli that are not nociceptive, i.e., not necessarily normally causing pain. Id. at 662. This is also known as

hyperaesthesia. "Aesthesia" means sensation, and "allodynia" means pain sensation. Id. Petitioner's hand pain exceeded the limits of where the hand fracture was. Id. at 663. Another term used for this is complex regional pain syndrome, and it is the most accepted term. Id. at 664. Chronic fatigue syndrome is related to regional pain syndrome if someone has fibromyalgia, but not if someone does not have fibromyalgia. Id. at 665. The incidence of chronic headache among persons with amplified pain is higher than the general population. Id. Headache pain is associated with chronic pain. Id. On June 9, 2008, petitioner's orthopedist, Dr. Uhl, used the term "complex regional pain syndrome" in reference to petitioner. Id. at 666.

Dr. Rosé agrees that petitioner has undifferentiated connective tissue disease ("UCTD"). Id. at 668. Undifferentiated connective tissue disease describes patients with symptoms also seen in inflammatory connective tissue diseases, i.e., lupus, scleroderma, dermatomyositis, and mixed connective tissue disease. Patients with UCTD have some of the specific symptoms or laboratory tests of connective tissue diseases but do not meet the criteria for any particular connective tissue disease. Id. That is why their disease is "undifferentiated." Id. at 669. Dr. Rosé, in referring to specific symptoms petitioner has, meant her Raynaud's syndrome. Petitioner has antinuclear antibodies, low titer lupus anticoagulant by the hexagonal test, and livedo (which represents a pathology in the dermal vessels, meaning the blood vessels of the deeper layers of the skin, which are dilated or inflamed, causing a bluish discoloration of the skin). Id. at 669-70.

Dr. Rosé said he knows Dr. Petri, petitioner's second rheumatologist, very well. Id. at 171. Dr. Petri made the diagnosis of UCTD based on petitioner's having Raynaud's, antinuclear antibodies, lupus anticoagulant, and livedo. Id. at 673-74. Dr. Rosé said that patients with UCTD have three possible outcomes: (1) developing a full-blown connective tissue disease that meets the criteria for diagnosis that were missing, (2) remaining as UCTD, or (3) having the UCTD fade away and disappear. Id. at 674-75. The most common time period when an adult with UCTD might develop a full-blown connective tissue disease is about five years. Id. at 679. The most common full-blown connective tissue disease is lupus. Id. at 680.

Dr. Rosé put the onset of petitioner's UCTD as April 2009 when she had the first positive ANA. Id. But petitioner could have been ANA positive before, in 2004, according to the false positive EBV test. Nothing in the record says when petitioner's Raynaud began. Dr. Rosé cited petitioner's exhibit 334, the Arbuckle article studying Army recruits' sera and discovering that they had ANA positivity way before they had clinical symptoms of lupus. Id. Petitioner has livedo reticularis, which means mimicking a mesh. Id. at 684. It is known to be associated with the presence of antiphospholipid syndrome or lupus anticoagulant. Id. at 685. Dr. Rosé's opinion is that petitioner has an autoimmune disease called UCTD. Id. at 685-86. UCTD is probably inflammatory in some of its manifestations. Id. Raynaud is not inflammatory, but arthritis is inflammatory. Id. at 687.

Dr. Rosé said he was having difficulties establishing the source of petitioner's joint pain. Id. at 688. Two rheumatologists examined petitioner and did not report objective evidence of

arthritis, i.e., joint swelling or limitation of range of motion. Id. Petitioner complained of joint pain that was arthralgic. Id. at 688-89. However, petitioner also had pain amplification syndrome and may have had something similar to fibromyalgia, making it difficult for Dr. Rosé to say it was arthralgia. Id. at 689. Her joint pain could be attributed to the UCTD or to her other pain amplification symptoms. Id. Dr. Rosé pointed out one negative predictor of petitioner's UCTD evolving into a full-blown connective tissue disease: her negative anti-DNA antibody. Id. The presence of anti-DNA antibody when someone has UCTD is very specific for lupus, but petitioner had negative anti-DNA antibody. Id. at 690. In addition, it has been five years since petitioner was tested and she has not developed a full-blown syndrome. It looks like she has been lucky not to evolve into a full-blown connective tissue disease, i.e. lupus, scleroderma, dermatomyositis, or rheumatoid arthritis. Id. Dr. Rosé would put petitioner in the non-evolving UCTD group. Id. at 691.

Dr. Rosé agrees that petitioner has a low positive and a moderately positive lupus anticoagulant. Id. at 711-12. But petitioner was positive for only one of the tests for the lupus anticoagulant, the most sensitive of all of them. Id. at 713. Whenever you increase sensitivity, however, you lose specificity. Id. Doctors did two tests for petitioner's lupus anticoagulant, the hexagonal and the mixing test. Id. at 715. The hexagonal was positive but the mixing test was negative. Id. Dr. Rosé does not think petitioner has gastrointestinal manifestations of UCTD. Id. at 717. None of the two rheumatologists who saw petitioner reported that petitioner had a malar rash. Id. at 718. Dr. Nichter wrote a letter dated March 1, 2010 stating that petitioner's occasional vesicular rash did not meet the criteria for a butterfly rash of SLE. Id. at 719-20. Dr. Petri prescribed Plaquenil, a mild immune suppressor, for petitioner. Id. at 721. Petitioner tried Plaquenil for several days but did not see any improvement. Id. at 724. Dr. Rosé said it would have taken at least three to four months for petitioner to see any improvement in her Raynaud's disease. Id.

Dr. Rosé said that petitioner's incongruent test results in 2004 for viral capsid antibodies and the Epstein-Barr nuclear antigen are possibly due to immunofluorescent interference from the presence of antinuclear antibodies. Id. at 767. The presence of antinuclear antibodies preceding clinical disease is very common. Id. at 768. His opinion is that petitioner's two Gardasil vaccinations played no role in the development of her positive antinuclear antibodies and undifferentiated connective tissue disease. Id. He does not know of any scientifically reliable evidence that Gardasil vaccine causes undifferentiated connective tissue disease. Id. at 771.

Dr. Rosé agreed that petitioner's gait could be described as astasia-abasia and that she had conversion disorder. Id. at 786. Conversion disorder is not the same as malingering. Id. at 788. Dr. Rosé attempted to explain why both Dr. Shoenfeld and the psychiatrist Dr. Sandler missed the diagnosis of conversion disorder. Id. Dr. Rosé repeated Dr. Shoenfeld's comment in one of his responses that "he has no business looking at the gait." Dr. Rosé said Dr. Shoenfeld was probably right. Doctors should do physical examinations, but they have so many other things to do that they do not do physical examinations. Id. Dr. Rosé thought Dr. Sandler, the

psychiatrist who saw petitioner in September 2009, wanted to help her with hypnosis and other treatments. Dr. Rosé continued, "[i]t's not that he completely dismissed that she had some psychological problem of whatever cause. . . ." Id.

Dr. Rosé testified that petitioner's gait problem had nothing to do with her UCTD. Id. at 789. He could not explain her gait disorder as being caused by any inflammatory or organic disease. Id. Petitioner's variable strength and weakness during physical examinations also suggests a nonorganic cause. Id. at 790. He would call this variability somatization. Id. at 791. Conversion disorder is classified under somatoform disorders, meaning psychosomatic. Id. As for POTS, the majority of POTS cases have not yet been proven to be autoimmune. Id. at 792. POTS is not associated with undifferentiated connective tissue disease. Id. at 793. Dr. Peter Rowe, a Johns Hopkins specialist, whom Dr. Rosé knows, tested petitioner on August 11, 2010, and he discussed in his notes her loose-jointedness in the context of his using the phrase "connective tissue". Id. at 794-95. This is not the same as undifferentiated connective tissue disease. Id. at 795. The reason Dr. Rowe was discussing petitioner's loose-jointedness is that individuals with loose joints can have more loose blood vessels which allow more blood pooling when they stand up, leading to POTS. Id.

Dr. Rosé discussed R. Ex. BBBBBBB (7B), which is the Wang article[52] for which petitioner filed an abstract marked as P. Ex. 88. Id. at 801. Wang does not say that POTS is an autoimmune disease. Id. at 803. Wang and his co-authors were looking for things intrinsic to the heart to which autoantibodies could be made. Id. at 804. In Wang's experiment, proteins were the targets of the autoantibodies. Id. at 807. Dr. Rosé said none of what Wang did has anything to do with POTS, which is a neurocardiopathy, not a cardiopathy. Id. POTS is not an intrinsic cardiac disease. Id. at 811. Dr. Rosé is in the mainstream of the medical community that views POTS as an autonomic nervous system disease, not a cardiac autoimmune disease. Id.

The undersigned asked Dr. Wiznitzer, respondent's expert neurologist, to comment. Id. at 812. He said the total study population for Wang was seven controls and ten subjects. Wang and his co-authors found 18 unique spots in the POTS patients, but there were 16 spots that the controls shared with the POTS patients, which means that the controls had autoantibodies that were of no functional consequence vis a vis POTS. Id. They were of no functional consequence because the controls did not have clinical symptoms of POTS. Everyone has some antibodies

[52] Wang, X.L. et al., Autoimmunoreactive IgGs from patients with postural orthostatic tachycardia syndrome, 6 Proteomics Clin Appl 615-25 (2012). Wang notes that anti-ganglionic acetylcholine receptor (AChR) antibodies are present in 10-15% of POTS patients. Id. at 621. AChR was not one of the cardiac membrane proteins Wang's study detected because the AChR in hearts are of the muscarinic, not the neuronal nicotinic, subtype. Id. Wang, in a section titled "Limitations of the study," identifies a list of 40 unique cardiac membrane proteins that were potential targets of autoantibodies in POTS patients, but states that further confirmation is necessary with a much larger number of patients and controls to make any conclusion. Id. at 624. Another limitation Wang mentions is he did not know the functional consequence of IgG binding to specific target cardiac membrane proteins, the same point he makes in the conclusion of his study as well. Id. He suggests further studies be done. Id.

circulating that have an autoantibody nature. Id. Where the antibodies bind in terms of the proteins involved in Wang, they were not part of the regulation of the autonomic nervous system. Id. at 813. If Dr. Wiznitzer had designed this study, he would have needed a much larger population, not seven controls, and he would have chosen another one or two organs in the body, not the heart, to see if there were similar cross-reactivity or these were just nonspecific antibodies in the bloodstream. Id. All Wang did was find something and say he does not know what it means. Id. at 814. Just because an autoantibody binds does not mean it causes problems. All seven controls in Wang's study had evidence of autoantibodies but did not have POTS. Id. Dr. Wiznitzer said that all of us carry antinuclear antibodies and about 10 percent of the population carries them without disease. Id. at 815.

Dr. Shoenfeld contributed to the discussion and said that all of us have autoantibodies, called natural autoantibodies, in very low titers. Id. at 817. Our body uses them to clean out our system. They clean DNA by binding to them and taking them out. It is not surprising to find a normal person binding to different proteins in his body. Id. Dr. Shoenfeld stated it was possible that 100 percent of POTS was autoimmune, but he does not know yet. Id. at 819. However, he admitted that POTS can be non-autoimmune: "I don't say that POTS cannot be non-autoimmune." Id.

Dr. Rosé stated that the Wang paper concluding the autoantibodies they found in the ten subjects and seven controls were pathogenic is still too premature. Id. at 821. Wang himself said his study was preliminary or a pilot. Id. Dr. Rosé stated that testing of petitioner for antibodies showing her POTS was autoimmune were negative. Id. at 822. Some doctors consider chronic fatigue syndrome to be autoimmune. Id. at 826. The most common cause of chronic fatigue is sleep deprivation. Id. Dr. Rosé mostly deals with chronic fatigue syndrome as a sleep abnormality. Id. at 827. Doctors do not use immunosuppressive therapies to treat chronic fatigue syndrome. Id. Chronic fatigue syndrome and POTS overlap in symptoms. Id. at 830. He does not consider chronic fatigue syndrome to be autoimmune. Id. at 831. He has a lot of patients with chronic fatigue syndrome. Id. Dr. Rosé's opinion is that HPV vaccine had nothing to do with petitioner's symptoms. Id. at 833.

On cross-examination, petitioner's counsel asked Dr. Rosé if his opinion that petitioner's HPV vaccination did not cause her chronic fatigue syndrome would change if there were evidence that petitioner's neighbor Natalie Rowen had the same symptoms after Gardasil vaccination. Id. at 841. Dr. Rosé said no.

On redirect examination, Dr. Wiznitzer discussed the psychiatrist Dr. Sandler's failure to find that petitioner had evidence of a psychosomatic condition and, therefore, could not have had a conversion disorder. Id. at 848. The Diagnostic and Statistical Manual, 5th ed. ("DSM-V"), from the American Psychiatric Association, modified the definition of "conversion disorder" to stress the primacy of the neurologic examination and stated definitively that a psychological problem may not be identifiable at the time of diagnosis. Id. at 848-49. Neurologists believe that they do not need psychiatric input to diagnose conversion disorder. Id. at 849. A conversion

disorder is particularly appropriate if the patient has astasia-abasia. Id. Petitioner's father then asked if Dr. Nichter, petitioner's neurologist, ever used the term "conversion disorder" in his notes, and the undersigned said no. Id. at 850. Dr. Wiznitzer said "no" in agreement but added that Dr. Nichter described all the features of conversion disorder in his notes. Id. Petitioner's father then said he would not deny petitioner had a strange gait, which could not be explained physiologically,[53] but, he said, at no point did petitioner's treating physicians label her as having a conversion disorder.[54] Id. at 850-51. Petitioner's father added that he was involved with all of petitioner's treating physicians, and Dr. Wiznitzer was not. Id. at 851. Dr. Wiznitzer replied that multiple treaters for petitioner used "astasia-abasia" to describe her gait. He added that astasia-abasia is a recognized movement disorder that is part of conversion disorder. Id.

In repeated criticism of the Wang article (P. Ex. 88 for the abstract; R. Ex. BBBBBBB for the full article), Dr. Wiznitzer noted that not all the subjects in Wang's analysis had identified immunoreactive spots. Id. at 853. He said that no subject had the same spot. In other words, it was not as if all seven subjects had the same spot. Id. The authors did not describe whether the individuals they studied had high or low titers. Id. at 853-54. Dr. Wiznitzer called Wang's article "a preliminary hypothesis-generating study." Id. at 854.

Petitioner's father then asked Dr. Wiznitzer questions, beginning with the statement that he is a cardiac surgeon, not a neurologist. Id. at 856. He asked how often Dr. Wiznitzer sees POTS patients, and Dr. Wiznitzer replied about once a month. Id. Petitioner's father said that his medical center's pediatric neurology clinic consisting of four or five pediatric neurologists sees POTS only once a year. Id. at 857. His attention then turned to Dr. Wiznitzer's prior testimony about blood pressure, and Dr. Wiznitzer clarified that when voltage-gated calcium channel 1.2 is dysfunctional, it is associated either with a rhythm disturbance, i.e., an arrhythmia, or with an abnormality such as congestive heart failure or cardiac hypertrophy. Id. at 857-58.

Dr. Shoenfeld gave rebuttal testimony. Id. at 862. He said that before she received Gardasil vaccine, petitioner did not have POTS, chronic fatigue syndrome, UCTD, or livedo. Id.

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[53] "Physiologic" means "normal; not pathologic, characteristic of or conforming to the normal functioning or state of the body. . . ." Dorland's at 1444. What petitioner's father meant when he said he would not deny petitioner had a strange gait that could not be explained physiologically, he meant there was no normal explanation for her strange gait.

[54] Petitioner's father is incorrect. Petitioner's pediatrician, Dr. Kennette, twice mentioned conversion syndrome in her notes, and one of petitioner's physical therapists mentioned conversion syndrome in her notes. On April 24, 2009, petitioner's father phoned Dr. Kennette's office, concerned that petitioner had muscle pains. Dr. Kennette's note questioned whether petitioner's symptoms represented a myositis syndrome or conversion syndrome because of petitioner's astasia-abasia. Med. recs. Ex. 12, at 40. On May 5, 2009, Dr. Kennette filled out a child and adolescent psychiatric telephone consultation request to Four Winds Foundation, asking if a psychiatrist would see petitioner for the working diagnosis of conversion syndrome. Id. at 48. On July 14, 2009, physical therapist Adrienne Fil noted that petitioner's physical presentation with mobility continued to be incongruent with objective measurements, raising the possibility of conversion disorder. Med. recs. Ex. 11, at 8.

at 863. Petitioner had three autoantibodies: ANA, lupus anticoagulant, and rheumatoid factor. Id. at 864. Petitioner had hair loss, which is an additional criterion for lupus. She had rash, which some said was butterfly but others said it was not butterfly. She had constipation. She had joint pains and swollen joints. Arthralgia is also a criterion for lupus. Id. Petitioner had smell and taste issues, sleeping disturbances, and cognitive impairment. Id. at 864-65. She never had any of these manifestations before receiving Gardasil vaccine, and all these manifestations occurred within two months or ten weeks of the Gardasil vaccination. Id. at 865.

Dr. Shoenfeld continued that, before Gardasil vaccination, petitioner was active, and played soccer. After vaccination, she was limited in her physical activity. His hypothesis, which he called plausible, is that petitioner had an autoimmune response to Gardasil. He stated that vaccines can cause autoimmune responses by many mechanisms. Dr. Shoenfeld believes, in this case, that the vaccine antigen crossreacted with different constituents in petitioner's body, existing in her heart and calcium channels, producing autoantibodies. Id. These autoantibodies caused dysfunction of her autonomic nervous system, the sympathetic, and parasympathetic affecting her heart, and the peripheral nervous system. Id. at 866. He said the peripheral nervous system and the autonomic nervous system innervate the heart, which belongs to the autonomic nervous system. Id.

Dr. Shoenfeld denied there is evidence that petitioner had antinuclear antibodies before she received Gardasil vaccine. Id. at 868. Dr. Shoenfeld accused respondent's experts of stating that conversion reaction caused all of petitioner's symptoms, including UCTD, livedo, lupus anticoagulant, ANA, and rheumatoid factor. Id. at 868-69. Dr. Shoenfeld denied that petitioner had a pre-existing infection before her symptoms began because she did not have an increase in white blood cells on testing of her blood. Id. at 869. Petitioner's C-reactive protein ("CRP") was normal in all her studies. Id. at 870. Dr. Shoenfeld said that CRP is normal in lupus, but increased when there is infection. Id.

Dr. Shoenfeld said that antiphospholipid syndrome is not an inflammatory disease. Id. at 871. Dr. Shoenfeld denied petitioner ever had an infection in the third week of February 2009. Id. The only pre-symptom event that Dr. Shoenfeld would accept was Gardasil vaccine. Id. at 872. He said that Gardasil can cause POTS, and that POTS and UCTD are autoimmune diseases. Id. at 872-73. The failure of doctors and scientists to find an autoantibody does not exclude autoimmune etiology. Id. at 874. In only 40 percent of many classic autoimmune diseases do doctors find autoantibodies. Id. This just means the doctors did not do all the work to find them. Id. at 874-75. Dr. Shoenfeld mentioned that he has never had a private practice. Id. at 875. Dr. Shoenfeld said that livedo is associated with antiphospholipid syndrome. Id.

Dr. Shoenfeld was working on a paper studying 100 UCTD patients with no definite autoimmune disease compared to 100 controls. Id. at 880-81. The authors discovered a significantly higher number of patients with UCTD who had a prior vaccination in comparison to the 100-person control group. Id. at 881.

Dr. Shoenfeld stated that petitioner's pre-vaccination testing showing a weakly positive Epstein-Barr virus nuclear antigen did not mean that she had antinuclear antibody. Id. at 882. She was not tested for antinuclear antibody before the vaccination. It appeared after the vaccination. Id. Petitioner did not have anti-double stranded DNA, but she did have anticardiolipin and antiphospholipid. Id. at 884. Therefore, petitioner is at great risk of developing autoimmune disease and belongs in the evolving group. Id.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]"

Althen, 418 F.3d at 1278.

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioner must show not only that but for Gardasil, she would not have had all the illnesses about which she complains, but also that the vaccine was a substantial factor in causing her illnesses. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The question arose whether the onset of petitioner's undifferentiated connective tissue disease ("UCTD") arose before or after Gardasil vaccination, raising the question of whether Gardasil significantly aggravated her UCTD. Section 300aa-33(4) defines "significant aggravation" as follows:

> The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

42 U.S.C. § 300aa-33(4).

Because of the multiple illnesses petitioner alleged through her father when he was the initial petitioner plus the additional illnesses that petitioner's expert Dr. Shoenfeld raised at the hearing, the undersigned will discuss each illness individually.

Migraine headaches

The original petitioner (petitioner's father) alleged in the petition that Gardasil administered December 3, 2008 caused his daughter (the current petitioner) severe headaches, photophobia, phonophobia, dizziness, and gait disturbances. These all fall under the rubric of migraine headache. Petitioner had these symptoms in the beginning of June 2007, more than one year before she received her first Gardasil vaccination on August 26, 2008. On June 6, 2007, she complained to her pediatrician Dr. Karen Kennette that when she stood up, she felt very dizzy. She felt as if she were on a boat. Her gait was slightly slow secondary to her headaches. Dr. Kennette examined petitioner in a dark room where petitioner was wearing dark sunglasses. Because the headache persisted, petitioner underwent on June 7, 2007 a brain MRI, which was normal. On June 8, 2007, petitioner's mother called Dr. Kennette to say petitioner was still complaining of a headache and was absolutely no better. She had to lie in a dark room. On June 8, 2007, petitioner went to Albany Medical Center Emergency Department, where petitioner gave a history that three weeks earlier, she was refereeing a soccer game and felt as if her head were spinning. She also had a headache and had to sit down. The episode resolved. But a week before she came to the hospital, she had another headache similar to the first one. It was bilateral and frontal. Her dizziness was mild. But she also had photophobia, phonophobia, and associated nausea. The neurologist on call diagnosed migraine.

On August 14, 2007, petitioner complained to Dr. Kennette of fatigue.

Between petitioner's first Gardasil on August 26, 2008, and her second Gardasil on December 3, 2008, she had no complaints other than injury to her left ankle and a fractured left fibula.

Two and three-quarter months after the second Gardasil, petitioner saw Dr. Kennette on Thursday, February 26, 2009, complaining of a bad headache she had on February 21, 2009, weak pain, nausea, fever, dizziness, and photophobia. Her father prescribed on February 19, 2009 Cipro for presumed sinusitis. Some of the possible side effects of Cipro include headache, dizziness, pain, nausea. See n.8 supra. Petitioner started taking Cipro two days before the onset of her headache. Dr. Kennette diagnosed petitioner with photophobia, bitemporal squeezing pain, and migraine. Petitioner walked out of Dr. Kennette's office holding onto her mother's arm. Dr. Kennette presumed petitioner had sinusitis.

Petitioner's headache continued until she went to Albany Medical Center Emergency Department on March 6, 2009 where she saw a number of doctors including the neurologist Dr. Nichter. She improved briefly the next day, but her headaches continued. On March 31, 2009,

Dr. Kennette's office received a telephone call from petitioner's mother. She wanted the lot number of Gardasil that petitioner had received. She said that petitioner's headaches had been ongoing since petitioner received Gardasil. In addition, a friend had received the same lot number of Gardasil and she had the same problem as petitioner.

Also on March 31, 2009, Dr. Kennette filled out a VAERS (Vaccine Adverse Event Reporting System) form, writing that petitioner received Gardasil on December 3, 2008 and the onset of her vaccine reaction on February 21, 2009 or eleven weeks and three days later. Med. recs. Ex. 12, at 34. The only adverse event Dr. Kennette described was protracted headache. Id. Dr. Kennette states petitioner recovered. Id.

Dr. Shoenfeld, petitioner's expert, testified at the hearing that migraine headache is not an autoimmune disease, but a neurovascular one. He did not testify that Gardasil caused petitioner's migraine headache.

Althen analysis

Petitioner failed to prove that Gardasil can cause migraine headache (prong one of Althen). Petitioner failed to prove that Gardasil did cause her migraine headache (prong two of Althen). Petitioner failed to prove that two and three-quarter months after Gardasil until the onset of migraine headache is an appropriate interval to prove causation of migraine headache (prong three of Althen).

POTS

Dr. Shoenfeld testified that petitioner's POTS began two months to 10 weeks after her second Gardasil. However, petitioner did not have the symptoms of POTS until either September or October 2009 according to petitioner's medical records, petitioner's father's summary of the medical records, petitioner's affidavit, and petitioner's father's affidavit. The hallmark of POTS is feeling faint when rising from a supine position, when blood pressure becomes low and the heart rate rises. Petitioner did not have these symptoms until she had been sitting in a wheelchair for seven months. The first notice of petitioner's swaying, saying her legs felt like jello, was on April 6, 2009, which was four months after her second Gardasil. She had no problem getting up. Her problem was leaning when she walked. Dr. Nichter diagnosed her with a wobbly gait, but no vertigo or ataxia. By April 22, 2009, petitioner felt her legs were not part of her body. She was under a lot of stress at home because her maternal grandmother died and her father had surgery.

According to petitioner's father's summary of the medical records, petitioner had been seeing black spots and then falling to the floor with tachycardia on October 6, 2009. R. Ex. AAAAAAA, at 3. Petitioner's affidavit recounts the same history. P. Ex. 554, at 4. Petitioner's father's affidavit also recounts the same history. P. Ex. 551, at ¶ 35.

Dr. Wiznitzer testified that petitioner's POTS began late September or early October 2009 due to deconditioning. His testimony is in accordance with medical literature[55] that both parties filed in this case. Dr. Shoenfeld, on the other hand, insisted that petitioner's POTS began two months to 10 weeks after petitioner's second Gardasil. This makes no sense in light of the failure of petitioner to manifest symptoms of POTS until late September or early October.

The complicating picture in Dr. Shoenfeld's analysis of petitioner's medical history is that she was manifesting symptoms in April 2009 that had no biologic explanation, what petitioner's father called a strange gait that had no biophysiologic explanation. Her conversion disorder or psychosomatic symptoms seem to have been in imitation of Natalie Rowan's taking to a wheelchair after receiving the same lot of Gardasil as petitioner. Natalie lived less than two blocks away from petitioner. Petitioner's father testified, and the medical history from petitioner's mother's statements confirms, that petitioner's father was influenced to file suit because of Natalie Rowan's suit in the Vaccine Program.

Dr. Shoenfeld based his rejection of petitioner's having conversion disorder on the psychiatrist Dr. Sandler's meeting with petitioner on September 1, 2009, one week after petitioner's parents asked him to determine if petitioner had psychological symptomatology. Dr. Sandler did not read petitioner's medical records. He did not examine petitioner. Because petitioner looked him in the eyes when she spoke and she was alert, oriented, and very cooperative, he concluded she did not have psychosomatic symptoms. This was not a valid basis for determining if petitioner were manifesting psychosomatic symptoms six months earlier. An opinion without a reasonable basis is worthless. Davis v. Sec'y of HHS, 20 Cl. Ct. 168, 173 (1990) ("conclusions . . . are only as good as the reasons and evidence that support them"). Yet Dr. Shoenfeld relied on Dr. Sandler's opinion, not only in his testimony, but also in the case report he and three co-authors published in 2014 on petitioner's case (Ex. 470, see n.53 supra).[56]

Seven of petitioner's treating doctors opined that her inability to walk, her variable and inconsistent weakness, and her inability to see were not manifestations of a physical illness: Dr. Sobeih, Dr. Nichter, Dr. Rheeman, Dr. Cornblath, Dr. Petri, Dr. Rowe, and Dr. Lindstrom. Three of them, Drs. Nichter, Rheeman, and Lindstrom, attributed petitioner's complaints to her inability to deal with stress. The Federal Circuit in Capizzano emphasized that the special masters are to evaluate seriously the opinions of petitioner's treating doctors since "treating

[55] For example: P. Ex. 485: Postural Tachycardia Syndrome (POTS) by P.A. Low, et al., 20 J Cardiovasc Electrophysiol 352-58, 356 (2009) (some POTS patients "may have a strong deconditioning component"); P. Ex. 532: The Postural Orthostatic Tachycardia Syndrome: Definitions, Diagnosis, and Management by Y. Kanjwal, et al., 26 PACE 1747-57, 1754 (2003) (prolonged immobilization is a potentially reversible cause of POTS); R. Ex. AAAA, Postural Tachycardia Syndrome: A Heterogeneous and Multifactorial Disorder by E.E. Benarroch, 87 Mayo Clinic Proc 12:1214-25, 2015 (2012) (physical deconditioning has an important role in POTS patients).

[56] Petitioner's father testified that petitioner did not have psychosomatic symptoms, but did admit that her strange gait had no physiological explanation. Dr. Shoenfeld did not rely on petitioner's father's opinion.

physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." 440 F.3d at 1326. See also Broekelschen v. Sec'y of HHS, 618 F.3d 1339, 1347 (Fed. Cir. 2010); Andreu v. Sec'y of HHS, 569 F.3d 1367, 1375 (Fed. Cir. 2009).

The undersigned finds that the onset of petitioner's POTS was in late September or early October 2009, 10 or 11 months after her second Gardasil.

The nature of petitioner's POTS also was controversial. Dr. Shoenfeld testified that petitioner's POTS was autoimmune. However, doctors tested her on two separate occasions to see if she had anti-ganglionic antibodies, and the results were both times negative. Dr. Shoenfeld said if they had tested her for other antibodies, they would have been positive. But that is pure speculation. The medical literature from Dr. Blitshteyn shows that the majority of POTS is not autoimmune. P. Ex. 426; R. Ex. OOOO. Dr. Shoenfeld said he would not deny that non-autoimmune POTS exists. The only evidence in this case is that petitioner's POTS is not autoimmune. Therefore, Dr. Shoenfeld has failed to prove that Gardasil caused petitioner's POTS because, in addition to giving an incorrect onset, his opinion was based on his assumption that petitioner's POTS was autoimmune.

Althen analysis

Petitioner has failed to prove that Gardasil can cause non-autoimmune POTS (prong one of Althen). Petitioner has failed to prove that Gardasil did cause her non-autoimmune POTS (prong two of Althen). Petitioner has failed to prove that 10 or 11 months after Gardasil is an appropriate interval to prove causation of non-autoimmune POTS (prong three of Althen).

Chronic Fatigue Syndrome

Dr. Shoenfeld testified that petitioner's sore throat the third week of February 2009 was the onset of her chronic fatigue syndrome. However, petitioner's father diagnosed her with sinusitis and gave her Cipro, an antibiotic. The undersigned sees no reason to doubt petitioner's father's diagnosis. Moreover, one would expect that someone with chronic fatigue syndrome would complain of fatigue. Only after she stopped sleeping due to her migraine headaches did she complain of fatigue. The undersigned accepts Dr. Wiznitzer's testimony that her chronic fatigue syndrome occurred after she had been sitting in a wheelchair for seven months because petitioner was deconditioned. Dr. Peter C. Rowe of Johns Hopkins made an interesting observation on August 11, 2010 that petitioner had a connective tissue phenotype which allowed excessive compliance in her dependent circulation and was a factor contributing to her orthostatic intolerance, along with her deconditioning, which in turn caused a loss of plasma volume.

Althen analysis

Petitioner has failed to prove that Gardasil can cause chronic fatigue syndrome (prong one of Althen). Petitioner has failed to prove that Gardasil did cause her chronic fatigue syndrome (prong two of Althen). Petitioner has failed to prove that 10 or 11 months after Gardasil is an appropriate interval to prove causation of chronic fatigue syndrome (prong three of Althen).

UCTD

Dr. Petri of Johns Hopkins diagnosed petitioner with undifferentiated connective tissue disorder ("UCTD") on December 4, 2009 in light of her positive ANA, Raynaud's disease, livedo, and lupus anticoagulant. The reason Dr. Petri diagnosed petitioner with UCTD was that petitioner did not have a discrete rheumatological disease. The onset of petitioner's UCTD was disputed at the hearing. Dr. Shoenfeld at first said the onset was after Gardasil because that was when doctors tested petitioner for ANA. Then he thought better of that statement in light of the fact that doctors had not tested petitioner for ANA before vaccination. Moreover, the Arbuckle article (P. Ex. 334) which showed that autoantibodies can be present in non-symptomatic lupus patients for up to 9.4 years earlier meant that petitioner likely had autoantibodies before she became symptomatic as well.

The undersigned finds the Arbuckle article persuasive in finding that petitioner probably had autoantibodies pre-Gardasil vaccination for which doctors did not test until after vaccination. Petitioner has a family propensity for rheumatologic disease as petitioner's mother has Raynaud's disease as well. As for Dr. Shoenfeld's opinion that Gardasil is the cause of petitioner's manifesting livedo around both knees and forearms sometime during 2009, which together with the positive antibody, lupus anticoagulant, and rheumatoid factor led to the diagnosis of UCTD, the Federal Circuit has held that timing is not enough. Grant, 956 F.2d at 1148. Even the fact that UCTD is an autoimmune disease is not sufficient to pin causation on Gardasil because UCTD manifests over time. See, e.g., Arbuckle, P. Ex. 334, at 1532: "Our results show that clinical SLE [lupus] is preceded by complicated autoimmune changes that are usually under way for many years before diagnosis."

The undersigned finds particularly interesting that in the case report Dr. Shoenfeld published in 2014, Dr. Shoenfeld did not emphasize petitioner's UCTD, but listed it as a minor criterion for his suggested criteria of ASIA. P. Ex. 470 at 3, 6. Most of Dr. Shoenfeld's discussion of petitioner's history in that case report revolves around POTS and CFS as major criteria supporting his ASIA theory. At some time between the publication of that case report and the hearing in this case, Dr. Shoenfeld elevated the importance of UCTD as one of the illnesses that Gardasil caused.

Of special note is that petitioner's treating rheumatologist Dr. Petri stated in her medical records that she could not connect petitioner's UCTD to Gardasil.

Petitioner has failed to prove that Gardasil can cause or significantly aggravate UCTD (prong one of Althen). Petitioner has failed to prove that Gardasil did cause or significantly aggravate her UCTD (prong two of Althen). Petitioner has failed to prove that clinical and laboratory substantiation of UCTD occurring months after Gardasil is an appropriate interval to prove causation or significant aggravation of UCTD (prong three of Althen).

Small Fiber Polyneuropathy

Dr. Shoenfeld mentioned another illness, small fiber polyneuropathy, which he thought petitioner might have although there is no proof that she has it since she has never manifested symptoms of it, and no treating doctor diagnosed her with it. Petitioner had the option of having tests done to prove that she has small fiber polyneuropathy but either she did not undergo the tests or, if she did, they proved negative. In either event, petitioner failed to prove she has small fiber polyneuropathy.

Althen analysis

Petitioner has failed to prove that Gardasil can cause small fiber polyneuropathy (prong one of Althen). Petitioner has failed to prove that Gardasil did cause small fiber polyneuropathy (prong two of Althen). Petitioner has failed to prove that an unknown interval between a presumed small fiber polyneuropathy after Gardasil is an appropriate interval to prove causation (prong three of Althen).

Petitioner has failed to make a prima facie case of causation in fact that Gardasil caused any of the illnesses alleged in the petition or the illnesses Dr. Shoenfeld added at the hearing.

The undersigned **DISMISSES** this case for failure to make a prima facie case.

CONCLUSION

This petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk of the court is directed to enter judgment herewith.[57]

IT IS SO ORDERED.

January 31, 2017
DATE

s/Laura D. Millman
Laura D. Millman
Special Master

[57] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.